Appendix A

Figure A1. Analytic framework for treatments for fecal incontinence

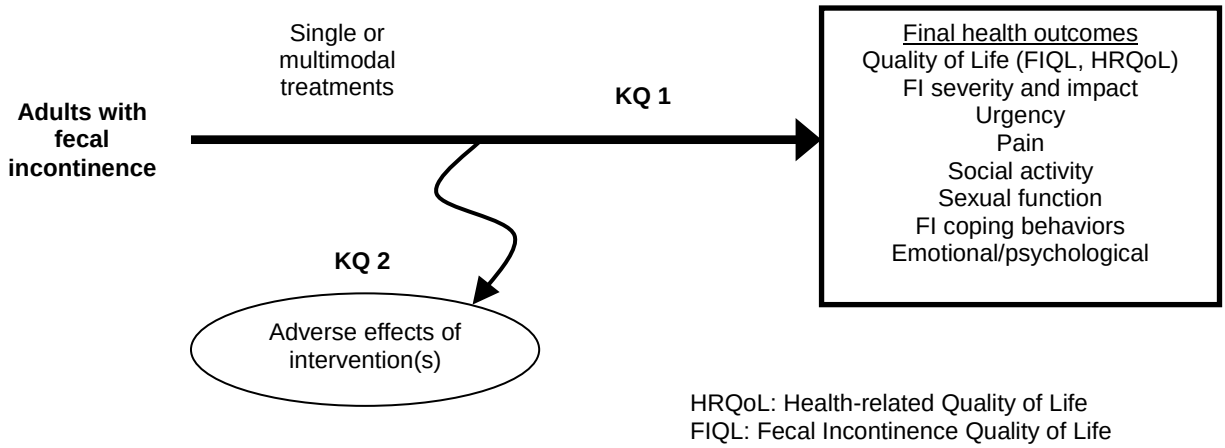

Figure A1 depicts the two key questions within the context of the PICOTS described in Table 1 of the report. The figure above illustrates how the use of single or multimodal treatments for fecal incontinence may improve outcomes for adults with fecal incontinence. This systematic literature review included adults who underwent treatment for fecal incontinence. The Key Question 1 final health outcome categories include quality of life (health-related or specific to fecal incontinence), FI severity and impact (continence measures), urgency, pain, social activity, sexual function, the use of coping behaviors to manage fecal incontinence, and emotional or psychological measures. Adverse effects of drugs or interventions may also occur at any point after the treatment is initiated; these were examined in Key Question 2.

Appendix B. Search Strings

Database: Ovid **MEDLINE**(R) <1980 to October Week 3 2014>

Search Strategy: RCTs

---

1 meta analysis as topic/
2 meta-analy$.tw.
3 metaanaly$.tw.
4 meta-analysis/
5 (systematic adj (review$1 or overview$1)).tw.
6 exp Review Literature as Topic/
7 or/1-6
8 cochrane.ab.
9 embase.ab.
10 (psychlit or psyclit).ab.
11 (psychinfor or psycinfo).ab.
12 or/8-11
13 reference list$.ab.
14 bibliograph$.ab.
15 hand search.ab.
16 relevant journals.ab.
17 manual search$.ab.
18 or/13-17
19 selection criteria.ab.
20 data extraction.ab.
21 19 or 20
22 review/
23 21 and 22
24 comment/
25 letter/
26 editorial/
27 animal/
28 human/
29 27 not (28 and 27)
30 or/24-26,29
31 7 or 12 or 18 or 23
32 31 not 30
33 randomized controlled trials as topic/
34 randomized controlled trial/
35 random allocation/
36 double blind method/
37 single blind method/
38 clinical trial/
39 clinical trial, phase i.pt.
40 clinical trial, phase ii.pt.
41 clinical trial, phase iii.pt.

42 clinical trial, phase iv.pt.
43 controlled clinical trial.pt.
44 randomized controlled trial.pt.
45 multicenter study.pt.
46 clinical trial.pt.
47 exp Clinical trials as topic/
48 or/33-47
49 (clinical adj trial$).tw.
50 ((singl$ or doubl$ or treb$ or tripl$) adj (blind$3 or mask$3)).tw.
51 placebos/
52 placebo$.tw.
53 randomly allocated.tw.
54 (allocated adj2 random$).tw.
55 49 or 50 or 51 or 52 or 53 or 54
56 48 or 55
57 case report.tw.
58 case report.tw.
59 letter/
60 historical article/
61 57 or 58 or 59 or 60
62 56 not 61
63 exp cohort studies/
64 cohort$.tw.
65 controlled clinical trial.pt.
66 epidemiologic methods/
67 limit 66 to yr=1971-1983
68 63 or 64 or 65 or 67
69 exp Fecal Incontinence/
70 f?ecal incontin*.ti,ab.
71 69 or 70
72 62 and 71
73 limit 72 to "all child (0 to 18 years)"
74 limit 73 to "all adult (19 plus years)"
75 72 not 73
76 75 or 74

Database: Ovid MEDLINE(R) without Revisions <1980 to October Week 3 2014>
Search Strategy: Obs & SRs

---

1 meta analysis as topic/
2 meta-analy$.tw. 3 metaanaly$.tw.
4 meta-analysis/
5 (systematic adj (review$1 or overview$1)).tw.
6 exp Review Literature as Topic/
7 or/1-6
8 cochrane.ab.
9 embase.ab.
10 (psychlit or psyclit).ab.
11 (psychinfor or psycinfo).ab.
12 or/8-11
13 reference list$.ab.
14 bibliograph$.ab.
15 hand search.ab.
16 relevant journals.ab.
17 manual search$.ab.
18 or/13-17
19 selection criteria.ab.
20 data extraction.ab.
21 19 or 20
22 review/
23 21 and 22
24 comment/
25 letter/
26 editorial/
27 animal/
28 human/
29 27 not (28 and 27)
30 or/24-26,29
31 7 or 12 or 18 or 23
32 31 not 30
33 Epidemiologic studies/
34 exp cohort studies/
35 exp case control studies/
36 Case control.tw.
37 (cohort adj (study or studies)).tw.
38 contro*.tw.
39 Cohort analy$.tw.
40 (Follow up adj (study or studies)).tw.
41 (observational adj (study or studies)).tw.
42 Longitudinal.tw.
43 or/33-42
44 exp *Fecal Incontinence/

45 f?ecal incontin*.ti.
46 44 or 45
47 32 or 43
48 46 and 47
49 limit 48 to ("all infant (birth to 23 months)" or "all child (0 to 18 years)")
50 limit 49 to ("all adult (19 plus years)" or "young adult (19 to 24 years)" or "adult (19 to 44 years)" or "young adult and adult (19-24 and 19-44)" or "middle age (45 to 64 years)" or "middle aged (45 plus years)" or "all aged (65 and over)")
51 48 not 49
52 50 or 51
53 limit 52 to (autobiography or bibliography or biography or clinical conference or comment or congresses or consensus development conference or dataset or dictionary or directory or editorial or in vitro or interactive tutorial or interview or lectures or legal cases or letter or news or newspaper article or patient education handout or periodical index or portraits or validation studies or video-audio media or webcasts)
54 52 not 53
55 32 and 54
56 limit 55 to yr="2007 -Current"
57 43 and 54
58 limit 57 to yr="2014 -Current"
59 (anal and incontin*).ti.
60 43 and 59
61 43 and 46 and 60
62 61 not 60
63 58
64 from 63 keep 1-33

Database: **Embase** <1996 to 2014 Week 43>
Search Strategy: RCTs

---

1 Clinical trial/
2 Randomized controlled trial/
3 Randomization/
4 Single blind procedure/
5 Double blind procedure/
6 Crossover procedure/
7 Placebo/
8 Randomi?ed controlled trial$.tw.
9 Rct.tw.
10 Random allocation.tw.
11 Randomly allocated.tw.
12 Allocated randomly.tw.
13 (allocated adj2 random).tw.
14 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13
15 Case study/
16 Case report.tw.
17 Abstract report/ or letter/
18 15 or 16 or 17
19 14 not 18
20 exp feces incontinence/
21 f?ec* incontinence.ti,ab.
22 20 or 21
23 limit 22 to "therapy (maximizes specificity)"
24 19 and 22
25 23 or 24
26 limit 25 to (embryo <first trimester> or infant <to one year> or child <unspecified age> or preschool child <1 to 6 years> or school child <7 to 12 years> or adolescent <13 to 17 years>)
27 limit 26 to (adult <18 to 64 years> or aged <65+ years>)
28 25 not 26
29 27 or 28
30 limit 29 to (book or book series or conference abstract or conference paper or conference proceeding or "conference review" or editorial or letter or note or report or "review" or short survey or trade journal) (747)
31 29 not 30 (893)

Database: **Embase** <1996 to 2014 Week 43>
Search Strategy:Obs and SRs

---

1 exp cohort analysis/ (174551)
2 exp longitudinal study/ (63150)
3 exp prospective study/ (242937)
4 exp follow up/ (756554)
5 cohort$.tw. (402905)
6 1 or 2 or 3 or 4 or 5 (1292797)
7 exp case-control study/ (84810)
8 (case$ and control$).tw. (358942)
9 7 or 8 (386956)
10 (case$ and series).tw. (126465)
11 exp review/ (1524716)
12 (literature adj3 review$).ti,ab. (165004)
13 exp meta analysis/ (79651)
14 exp "Systematic Review"/ (80673)
15 11 or 12 or 13 or 14 (1686250)
16 (medline or embase or pubmed or cinahl or amed or psychlit or psychinfo or scisearch or cochrane).ti,ab. (110973)
17 retracted article/ (6623)
18 16 or 17 (117548)
19 15 and 18 (87911)
20 (systematic$ adj2 (review$ or overview)).ti,ab. (77973)
21 (meta?anal$ or meta anal$ or metaanal$ or metanal$).ti,ab. (84784)
22 19 or 20 or 21 (176214)
23 exp *feces incontinence/ (4452)
24 f?ecal incontin*.ti. (2291)
25 23 or 24 (4492)
26 limit 25 to (meta analysis or "systematic review") (67)
27 22 and 25 (129)
28 26 or 27 (143)
29 6 or 9 or 10 or 28 (1684571)
30 25 and 29 (1257)
31 limit 30 to yr="1980 -Current" (1257)
32 limit 31 to (embryo <first trimester> or infant <to one year> or child <unspecified age> or preschool child <1 to 6 years> or school child <7 to 12 years>) (153)
33 limit 32 to (adult <18 to 64 years> or aged <65+ years>) (47)
34 31 not 32 (1104)
35 33 or 34 (1151)
36 limit 35 to (book or book series or conference abstract or conference paper or conference proceeding or "conference review" or editorial or erratum or letter or note or report or "review" or short survey or trade journal) (522)
37 35 not 36 (629)
38 15 and 25 (718)
39 28 (143)

40 limit 39 to yr="2007 -Current" (97)
41 limit 40 to (book or book series or conference abstract or conference paper or conference proceeding or "conference review" or editorial or erratum or letter or note or short survey or trade journal) (18)
42 from 37 keep 1-629 (629)
43 40 not 41 (79)
44 37 (629)
45 from 44 keep 1-629 (629)

Database: Cochrane Library
Search Strategy:
'Fecal Incontinence'* in title, abstract, keyword
*automatically also searches for 'faecal incontinence'

AMED: Allied and Complementary Medicine

AMED-RCTs
1 meta analysis
2 meta-analysis
3 meta analys$.tw
4 meta-analys$.tw
5 (systematic adj (review$1 or overview$1).tw
6 Or/1-5
7 Cochrane.ab
8 Embase.ab
9 (psychlit or psyclit).ab
10 (psychinfor or psycinfo).ab
11 Or/7-10
12 Reference list$.ab
13 Bibliograph$.ab
14 Hand search.ab
15 Relevant journals.ab
16 Manual search$.ab
17 Or/12-16
18 Selection criteria.ab
19 Data extraction.ab
20 18 or 19
21 Comment.tw
22 Letter.tw
23 Editorial.tw
24 Animal/
25 Humans/
26 25 not (24 and 25)
27 21-23,26
28 6 or 11 or 17 or 20

29 28 not 27
30 Randomized controlled trial/
31 Randomized controlled trial.tw
32 Random allocation/
33 Double blind method/
34 Single blind method/
35 Controlled clinical trial.pt
36 Randomized controlled trial.pt
37 Multicenter study.pt
38 Clinical trial.pt
39 Exp clinical trials
40 Or 30-39
41 (clinical adj trial$).tw
42 (singl$ or doubl$ or treb$ or tripl$).tw
43 42 adj (blind$3 or mask$3).tw
44 Placebos/
45 Placebo$.tw
46 Randomly allocated.tw
47 (allocated adj2 random$).tw
48 Or/41-47
49 40 or 48
50 Case report.tw
51 Letter.tw
52 Letter.pt
53 50 or 51 or 52
54 49 not 53
55 Exp cohort studies/
56 Cohort$.tw
57 Controlled clinical trial.pt
58 Epidemiologic methods/
59 55 or 56 or 57 or 58
60 Exp Fecal Incontinence/
61 F?ecal incontin*.ti,ab
62 60 or 61
63 54 and 62

AMED Observational
1 meta analysis
2 meta-analysis
3 meta analys$.tw
4 meta-analys$.tw
5 (systematic adj (review$1 or overview$1).tw
6 Or/1-5
7 Cochrane.ab
8 Embase.ab
9 (psychlit or psyclit).ab

10 (psychinfor or psycinfo).ab
11 Or/7-10
12 Reference list$.ab
13 Bibliograph$.ab
14 Hand search.ab
15 Relevant journals.ab
16 Manual search$.ab
17 Or/12-16
18 Selection criteria.ab
19 Data extraction.ab
20 18 or 19
21 Comment.tw
22 Letter.tw
23 Editorial.tw
24 Animal/
25 Humans/
26 25 not (24 and 25)
27 21-23,26
28 6 or 11 or 17 or 20
29 28 not 27
30 epidemiologic studies.tw
31 exp cohort studies/
32 exp case control studies/
33 case control studies/
34 retrospective studies or prospective studies or follow up studies
35 longitudinal studies/
36 case control.tw
37 (cohort adj (study or studies)).tw
38 Contro*.tw
39 Cohort analy$.tw
40 (follow up adj (study or studies)).tw
41 (observational adj (study or studies)).tw
42 Longitudinal.tw
43 Or/30-42
44 Exp fecal incontinence
45 F?ecal incontin*.ti
46 44 or 45
47 29 or 43
48 46 and 47

PedRO

Search strategy: fecal incontinence or faecal incontinence.

CINAHL: Cumulative Index to Nursing and Allied Health

#	Query	Limiters/Expanders	Last Run Via	Results
S11	S1 OR S2 OR S3 OR S4 OR S5 OR S6	Limiters - Clinical Queries: Therapy - High Sensitivity Narrow by SubjectAge: - all adult Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	418
S10	S1 OR S2 OR S3 OR S4 OR S5 OR S6	Limiters - Clinical Queries: Therapy - High Sensitivity Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	738
S9	S1 OR S2 OR S3 OR S4 OR S5 OR S6	Limiters - Published Date: 19800101-20141231 Narrow by SubjectAge: - all adult Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	855
S8	S1 OR S2 OR S3 OR S4 OR S5 OR S6	Limiters - Published Date: 19800101-20141231 Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	1,998
S7	S1 OR S2 OR S3 OR S4 OR S5 OR S6	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	2,285
S6	TI anal and incontinence	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	97
S5	TI faecal and incontinence	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	227
S4	TI fecal and incontinence	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	308

#	Query	Limiters/Expanders	Last Run Via	Results
S3	Anal incontinence	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	112
S2	(MH "Fecal Incontinence")	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	2,023
S1	fecal incontinence OR faecal incontinence	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	2,257

Appendix C. Excluded Studies (all studies)

Not a Direct FI Treatment Study (n=22)

1. Elsebae MM. A study of fecal incontinence in patients with chronic anal fissure: prospective, randomized, controlled trial of the extent of internal anal sphincter division during lateral sphincterotomy. World Journal of Surgery. 2007 Oct;31(10):2052-7. PMID 17665247.
2. Boccasanta P, Venturi M, Barbieri S, et al. Impact of new technologies on the clinical and functional outcome of Altemeier's procedure: a randomized, controlled trial. Diseases of the Colon & Rectum. 2006 May;49(5):652-60. PMID 16575620.
3. Zimmerman DD, Gosselink MP, Hop WC, et al. Impact of two different types of anal retractor on fecal continence after fistula repair: a prospective, randomized, clinical trial. Diseases of the Colon & Rectum. 2003 Dec;46(12):1674-9. PMID 14668594.
4. Ho YH, Seow-Choen F, Tan M. Colonic J-pouch function at six months versus straight coloanal anastomosis at two years: randomized controlled trial. World Journal of Surgery. 2001 Jul;25(7):876-81. PMID 11572027.
5. Ho YH, Yu S, Ang ES, et al. Small colonic J-pouch improves colonic retention of liquids--randomized, controlled trial with scintigraphy. Diseases of the Colon & Rectum. 2002 Jan;45(1):76-82. PMID 11786768.
6. Meyer S, Hohlfeld P, Achtari C, et al. Pelvic floor education after vaginal delivery. Obstetrics & Gynecology. 2001 May;97(5 Pt 1):673-7. PMID 11339914.
7. Chassagne P, Jego A, Gloc P, et al. Does treatment of constipation improve faecal incontinence in institutionalized elderly patients? Age & Ageing. 2000 Mar;29(2):159-64. PMID 10791451.
8. Ouslander JG, Simmons S, Schnelle J, et al. Effects of prompted voiding on fecal continence among nursing home residents. Journal of the American Geriatrics Society. 1996 Apr;44(4):424-8. PMID 8636590.
9. Deen KI, Grant E, Billingham C, et al. Abdominal resection rectopexy with pelvic floor repair versus perineal rectosigmoidectomy and pelvic floor repair for full-thickness rectal prolapse. British Journal of Surgery. 1994 Feb;81(2):302-4. PMID 8156369.
10. Miner PB, Donnelly TC, Read NW. Investigation of mode of action of biofeedback in treatment of fecal incontinence. Digestive Diseases & Sciences. 1990 Oct;35(10):1291-8. PMID 2209296.
11. Markland AD, Richter HE, Burgio KL, et al. Weight loss improves fecal incontinence severity in overweight and obese women with urinary incontinence. International Urogynecology Journal. 2011 Sep;22(9):1151-7. PMID 21567259.
12. Glazener CM, Herbison GP, MacArthur C, et al. Randomised controlled trial of conservative management of postnatal urinary and faecal incontinence: six year follow up. BMJ. 2005 Feb 12;330(7487):337. PMID 15615766.
13. Glazener CM, Herbison GP, Wilson PD, et al. Conservative management of persistent postnatal urinary and faecal incontinence: randomised controlled trial. BMJ. 2001 Sep 15;323(7313):593-6. PMID 11557703.
14. Glazener CM, MacArthur C, Hagen S, et al. Twelve-year follow-up of conservative management of postnatal urinary and faecal incontinence and prolapse outcomes: randomised controlled trial. BJOG: An International Journal of Obstetrics & Gynaecology. 2014 Jan;121(1):112-20. PMID 24148807.
15. Scaglia M, Delaini G, Destefano I, et al. Fecal incontinence treated with acupuncture - a pilot study. Autonomic Neuroscience: Basic and Clinical. 2009 28 Jan;145(1-2):89-92. PMID 2009022616.
16. Melenhorst J, Koch SM, Uludag O, et al. Is a morphologically intact anal sphincter necessary for success with sacral nerve modulation in patients with faecal incontinence? Colorectal Disease. 2008 Mar;10(3):257-62. PMID 17949447.

17. Chan MK, Tjandra JJ. Sacral nerve stimulation for fecal incontinence: external anal sphincter defect vs. intact anal sphincter. Diseases of the Colon & Rectum. 2008 Jul;51(7):1015-24; discussion 24-5. PMID 18484136.

18. Terra MP, Dobben AC, Berghmans B, et al. Electrical stimulation and pelvic floor muscle training with biofeedback in patients with fecal incontinence: a cohort study of 281 patients. Diseases of the Colon & Rectum. 2006 Aug;49(8):1149-59. PMID 16773492.

19. Allgayer H, Dietrich CF, Rohde W, et al. Prospective comparison of short- and long-term effects of pelvic floor exercise/biofeedback training in patients with fecal incontinence after surgery plus irradiation versus surgery alone for colorectal cancer: clinical, functional and endoscopic/endosonographic findings. Scandinavian Journal of Gastroenterology. 2005 Oct;40(10):1168-75. PMID 16165701.

20. Giordano P, Renzi A, Efron J, et al. Previous sphincter repair does not affect the outcome of repeat repair. Diseases of the Colon & Rectum. 2002 May;45(5):635-40. PMID 12004213.

21. Efron JE. The SECCA procedure: a new therapy for treatment of fecal incontinence. Surgical Technology International. 2004;13:107-10. PMID 15744681.

22. Jorge JM, Wexner SD, James K, et al. Recovery of anal sphincter function after the ileoanal reservoir procedure in patients over the age of fifty. Diseases of the Colon & Rectum. 1994 Oct;37(10):1002-5. PMID 7924704.

Off Topic (n=8)

1. Matzel KE, Stadelmaier U, Hohenfellner M, et al. Chronic sacral spinal nerve stimulation for fecal incontinence: long-term results with foramen and cuff electrodes. Diseases of the Colon & Rectum. 2001 Jan;44(1):59-66. PMID 11805564.

2. Santoro GA, Eitan BZ, Pryde A, et al. Open study of low-dose amitriptyline in the treatment of patients with idiopathic fecal incontinence. Diseases of the Colon & Rectum. 2000 Dec;43(12):1676-81; discussion 81-2. PMID 11156450.

3. Miller R, Bartolo DC, Locke-Edmunds JC, et al. Prospective study of conservative and operative treatment for faecal incontinence. British Journal of Surgery. 1988 Feb;75(2):101-5. PMID 3349291.

4. Wexner SD, Hull T, Edden Y, et al. Infection rates in a large investigational trial of sacral nerve stimulation for fecal incontinence. Journal of Gastrointestinal Surgery. 2010 Jul;14(7):1081-9. PMID 20354809.

5. Poirier M, Abcarian H, Nelson R. Malone antegrade continent enema: an alternative to resection in severe defecation disorders. Diseases of the Colon & Rectum. 2007 Jan;50(1):22-8. PMID 17115341.

6. Takahashi T, Garcia-Osogobio S, Valdovinos MA, et al. Extended two-year results of radio-frequency energy delivery for the treatment of fecal incontinence (the Secca procedure). Diseases of the Colon & Rectum. 2003 Jun;46(6):711-5. PMID 12794570.

7. Riss S, Stift A, Teleky B, et al. Long-term anorectal and sexual function after overlapping anterior anal sphincter repair: A case-match study. Diseases of the Colon and Rectum. 2009 June;52(6):1095-100. PMID 2009402353.

8. Ortiz H, Armendariz P, DeMiguel M, et al. Prospective study of artificial anal sphincter and dynamic graciloplasty for severe anal incontinence. International Journal of Colorectal Disease. 2003 Jul;18(4):349-54. PMID 12774251.

9. Thomas GP, Norton C, Nicholls RJ, et al. A pilot study of transcutaneous sacral nerve stimulation for faecal incontinence. Colorectal Disease. 2013 November;15(11):1406-9. PMID 2013702071.

No patient-reported Outcomes/Data Not Usable (n=19)

1. Bharucha AE, Edge J, Zinsmeister AR. Effect of nifedipine on anorectal sensorimotor functions in health and fecal incontinence. American Journal of Physiology - Gastrointestinal & Liver Physiology. 2011 Jul;301(1):G175-80. PMID 21493732.
2. Fox M, Stutz B, Menne D, et al. The effects of loperamide on continence problems and anorectal function in obese subjects taking orlistat. Digestive Diseases & Sciences. 2005 Sep;50(9):1576-83. PMID 16133954.
3. Cheetham MJ, Kamm MA, Phillips RK. Topical phenylephrine increases anal canal resting pressure in patients with faecal incontinence. Gut. 2001 Mar;48(3):356-9. PMID 11171825.
4. Vaizey CJ, Kamm MA, Roy AJ, et al. Double-blind crossover study of sacral nerve stimulation for fecal incontinence. Diseases of the Colon & Rectum. 2000 Mar;43(3):298-302. PMID 10733109.
5. Heymen S, Pikarsky AJ, Weiss EG, et al. A prospective randomized trial comparing four biofeedback techniques for patients with faecal incontinence. Colorectal Disease. 2000;2(2):88-92. PMID 2001409335.
6. Deen KI, Kumar D, Williams JG, et al. Randomized trial of internal anal sphincter plication with pelvic floor repair for neuropathic fecal incontinence. Diseases of the Colon & Rectum. 1995 Jan;38(1):14-8. PMID 7813338.
7. Oya M, Ortiz J, Grant EA, et al. A video proctographic assessment of the changes in pelvic floor function following three forms of repair for post-obstetric neuropathic faecal incontinence. Digestive Surgery. 1994;11(1):20-4. PMID 1995007677.
8. Tobin GW, Brocklehurst JC. Faecal incontinence in residential homes for the elderly: prevalence, aetiology and management. Age & Ageing. 1986 Jan;15(1):41-6. PMID 3953330.
9. Latimer PR, Campbell D, Kasperski J. A components analysis of biofeedback in the treatment of fecal incontinence. Biofeedback & Self Regulation. 1984 Sep;9(3):311-24. PMID 6525357.
10. Harford WV, Krejs GJ, Santa Ana CA, et al. Acute effect of diphenoxylate with atropine (Lomotil) in patients with chronic diarrhea and fecal incontinence. Gastroenterology. 1980 Mar;78(3):440-3. PMID 7351282.
11. Collins E, Hibberts F, Lyons M, et al. Outcomes in non-surgical management for bowel dysfunction. British Journal of Nursing. 2014 Jul 24-Aug 13;23(14):776-80. PMID 25062312.
12. Oom DMJ, Steensma AB, Van Lanschot JJB, et al. Is sacral neuromodulation for fecal incontinence worthwhile in patients with associated pelvic floor injury? Diseases of the Colon and Rectum. 2010 April;53(4):422-7. PMID 2010271195.
13. Lacima G, Pera M, Amador A, et al. Long-term results of biofeedback treatment for faecal incontinence: a comparative study with untreated controls. Colorectal Disease. 2010 Aug;12(8):742-9. PMID 19486084.
14. Oberwalder M, Dinnewitzer A, Nogueras JJ, et al. Imbrication of the external anal sphincter may yield similar functional results as overlapping repair in selected patients. Colorectal Disease. 2008 Oct;10(8):800-4. PMID 18384424.
15. Rasmussen OO, Puggaard L, Christiansen J. Anal sphincter repair in patients with obstetric trauma: Age affects outcome. Diseases of the Colon and Rectum. 1999 February;42(2):193-5. PMID 1999066424.
16. Orrom WJ, Miller R, Cornes H, et al. Comparison of anterior sphincteroplasty and postanal repair in the treatment of idiopathic fecal incontinence. Diseases of the Colon & Rectum. 1991 Apr;34(4):305-10. PMID 2007347.
17. Ctercteko GC, Fazio VW, Jagelman DG, et al. Anal sphincter repair: a report of 60 cases and review of the literature. Australian & New Zealand Journal of Surgery. 1988 Sep;58(9):703-10. PMID 3074772.
18. Myers JB, Hu EM, Elliott SP, et al. Short-term outcomes of Chait Trapdoor for antegrade continence enema in adults. Urology. 2014 Jun;83(6):1423-6. PMID 24703460.
19. Fleshman JW, Peters WR, Shemesh EI, et al. Anal sphincter reconstruction: anterior overlapping muscle repair. Diseases of the Colon & Rectum. 1991 Sep;34(9):739-43. PMID 1914735.

No Comparator (n=4)

1. Lombardi G, Del Popolo G, Cecconi F, et al. Clinical outcome of sacral neuromodulation in incomplete spinal cord-injured patients suffering from neurogenic bowel dysfunctions. Spinal Cord. 2010 February;48(2):154-9. PMID 2010106909.
2. MacLeod JH. Management of anal incontinence by biofeedback. Gastroenterology. 1987 Aug;93(2):291-4. PMID 3596165.
3. MacLeod JH. Biofeedback in the management of partial anal incontinence. Diseases of the Colon & Rectum. 1983 Apr;26(4):244-6. PMID 6839894.
4. Norton C, Kamm MA. Outcome of biofeedback for faecal incontinence.[Erratum appears in Br J Surg 2000 Feb;87(2):249]. British Journal of Surgery. 1999 Sep;86(9):1159-63. PMID 10504370.

Treatment Not FDA Approved (n=11)

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Appendix D. Risk of Bias Assessment Forms

Fecal Incontinence Randomized Controlled Trials

Author (year): **Title:**

Selection Bias	
Was method of randomization used to generate the sequence described in sufficient detail to assess whether it should produce comparable groups? (inadequate randomization?)	
Was method of treatment allocation adequate to keep treatment concealed until desired time? (inadequate allocation concealment)	
Were the groups similar at baseline regarding the most important prognostic indicators?	
Were all randomized participants analyzed in the group to which they were allocated?	
Risk of selection bias (inadequate randomization or allocation concealment):	**[Low, Unclear, High]**
Performance Bias	
Was the care provider blinded to the intervention?	Yes, No, NR
Were the participants blinded to the intervention?	Yes, No, NR
Nondrug interventions: Were interventions adequately defined so they could be replicated?	
Were co-interventions avoided? Differ by group?	
Was the intended blinding effective?	
Risk of performance bias due to lack of participant and personnel blinding, intervention definition & fidelity to treatment:	**[Low, Unclear, High]**
Detection Bias	
Were the outcome assessors blinded to the intervention?	Yes, No, NR, NA
Was the scale/tool used to measure outcomes validated, reliable?	
Was the timing of the outcome assessment similar in all groups?	
Were significance estimates for results appropriately corrected for multiple comparisons?	
Risk of detection bias due to lack of outcome assessor blinding, measurement of outcomes, statistical analysis:	**[Low, Unclear, High]**
Attrition Bias	
Was attrition lower than 20%? (Overall? By treatment group?)	Yes, No, NR, and %
Were reasons for incomplete/missing data adequately explained? (# assessed, dropped out, lost to followup)	
Was incomplete data handled appropriately?	
Risk of attrition bias due to amount, nature, or handling of incomplete outcome data?	**[Low, Unclear, High]**
Reporting Bias	
Were all outcomes in the Methods reported in Results or were only select outcomes reported?	
Were results (in tables and/or text) reported for all randomized patients for: Main outcomes? All outcomes? By treatment group?	
Risk of reporting bias due to selective outcome reporting?	**[Low, Unclear, High]**
Other Sources of Bias	
Are there other risks of bias? If yes, describe them	
Overall Risk of Bias Assessment by outcome(s)	**[Low, Moderate or High] and explanation (1-2 sentences)**

NA=not applicable; NR=not reported

Observational Studies

Question	Response	Criteria	Justification
	Internal Validity		
1. Study design: prospective, retrospective, or mixed?	Prospective ☐	Outcome had not occurred when study was initiated; information was collected over time	
	Mixed ☐	One group was studied prospectively; other(s) retrospectively	
	Retrospective ☐	Analyzed data from past records, claims	
2. Were inclusion/ exclusion criteria clearly stated?	Yes ☐	Clearly stated	
	Partially ☐	Some, but not all criteria stated or some not clearly stated.	
	No ☐	Unclear	
3. Were baseline characteristics measured using valid and reliable measures and are they equivalent in both groups?	Yes ☐	Valid measures, groups ~ equivalent	
	No ☐	Nonvalidated measures or nonequivalent groups	
	Uncertain ☐	Could not be ascertained	
4. Were important variables known to impact the outcome(s) assessed at baseline?	Yes ☐	Yes, most or all known factors were assessed	
	No ☐	Critical factors are missing	
	Uncertain ☐		
5. Is the level of detail describing the intervention adequate?	Yes ☐	Intervention sufficiently described	
	Partially ☐	Some of the above features.	
	No ☐	Intervention poorly described	
6. Is the selection of the comparison group appropriate?	Yes ☐	Other adults with fecal incontinence with similar etiologic, demographic, severity and comorbid features	
	No ☐		
7. Was the impact of a concurrent intervention or an unintended exposure that might bias results isolated?	Yes ☐	By inclusion criteria, protocol, or other means	
	Partially ☐	Some were isolated, others were not	
	No ☐	Important concurrent interventions were not isolated or prohibited	
8. Were there attempts to balance the allocation across groups? (e.g., stratification, matching or propensity scores)	Yes ☐	(*If yes, what method was used?)*	
	No ☐		
	Uncertain ☐	Could not be ascertained	
9. Were outcomes assessors blinded?	Yes ☐	Who assessed outcomes?	
	No ☐		
	Uncertain ☐	Not reported	
10. Were outcomes assessed using valid and reliable measures, and used consistently across all study participants?	Yes ☐	Measures were valid and reliable (i.e., objective measure, validated scale/tool); consistent across groups	
	Partially ☐	Some of the above features	
	No ☐	None of the above features	
	Uncertain ☐	Could not be ascertained.	
11. Was length of followup the same for all groups?	Yes ☐		
	No ☐		
	Uncertain ☐	Could not be ascertained	
12. Did attrition result in differences in group characteristics between baseline and followup?	Yes ☐	*(If yes, for which followup period(s)?)*	
	No ☐		
	Uncertain ☐	Could not be ascertained	
13. If dissimilar baseline characteristics, does the analysis control for	Yes ☐	What method?	
	No ☐		
	Uncertain ☐	Could not be ascertained	

Question	Response	Criteria	Justification
	Internal Validity		
baseline differences between groups?			
14. Were confounding and/or effect modifying variables assessed using valid and reliable measures across all study participants?	Yes ☐		
	No ☐		
	Uncertain ☐	Could not be ascertained (i.e., retrospective designs where eligible at baseline could not be determined)	
	NA ☐	No confounders or effect modifiers included in the study.	
15. Were important confounding and effect modifying variables taken into account in design and/or analysis? (e.g., matching, stratification, interaction terms, multivariate analysis, or other statistical adjustment)	Yes ☐		
	Partially ☐	Some variables taken into account or adjustment achieved to some extent.	
	No ☐	Not accounted for or not identified.	
	Uncertain ☐	Could not be ascertained	
16. Are statistical methods used to assess the primary outcome appropriate to the data?	Yes ☐	Statistical techniques used must be appropriate to the data.	
	Partially ☐		
	No ☐		
	Uncertain ☐	Could not be ascertained	
17. Is there suggestion of selective outcome reporting?	Yes ☐	Partial reporting of prespecified outcomes (e.g., secondary not primary outcomes; only significant outcomes; beneficial not adverse outcomes, etc.)	
	No ☐		
	Uncertain ☐	Could not be ascertained	
18. Was the funding source identified?	Yes ☐	Who provided funding?	
	No ☐		
	Uncertain ☐		
Overall Assessment			
Overall Risk of Bias Assessment	Low ☐	Results are believable taking study limitations into consideration	
	Moderate ☐	Results are probably believable taking study limitations into consideration	
	High ☐	Results are uncertain taking study limitations into consideration	

Appendix E. Common Fecal Incontinence Outcome Measures

Measure	Description	Scoring Range/Items	Best Score	Minimal Clinically Important Difference (MID) (if known)
Severity and Impact				
Browning and Parks Incontinence Score[1]	Degree: 4 categories (A) continent for solid/liquid, B) continent for solid/liquid, not gas, C) continent for solid, not liquid/gas, D) incontinent for solid/liquid/gas)	A-D 4 items	A	
Cleveland Clinic Fecal Incontinence Score/Wexner (CCFIS)[2]	Frequency: 5 categories (low: <1/month to high: >1/day) Consistency: 3 categories (gas, liquid, solid) Pad use; Lifestyle alteration	0-20 5 items	0	-2 to -3 points[3]
Fecal Incontinence and Continence Assessment (FICA)[4]	Frequency (low: ≤1/month to high: ≥2-3/week); Consistency/Amount (gas only/soiling, small amount of stool, moderate/large amount of stool); Pad use; Urgency	1-12 4 items	1	
Fecal Incontinence Severity Instrument (FISI)[5]	Frequency: 6 categories (low: 1-3/month to high:>2/day) Consistency: 4 categories (gas, liquid, solid, mucous)	0-61 4 items	0	-4 points[6]
Miller's Incontinence Score[7]	Frequency: 3 categories (low: <1/month to high: >1/week) Consistency: 3 categories (gas, liquid, solid)	0-18 3 items	0	
Pescatori Fecal Incontinence Score[8]	Frequency: 3 categories (occasionally, weekly, daily) Consistency: 3 categories (gas, liquid, solid)	0-6 3 items	0	
St. Mark's Fecal Incontinence Score[9]	Frequency: 4 categories (low: <1/month; high: most days); Consistency: 3 categories (gas, liquid, solid); Urgency; Difficulty cleaning; Soiling	0-13 6 items	0	
Vaizey Fecal Incontinence Score[10]	Frequency: 5 categories (low: 1/month; high: every day); Consistency: 3 categories (gas, liquid, solid); Pad use; Urgency; Lifestyle alterations; Antidiarrheal medication use	0-24 7 items	0	-5 points[11] -3 to -5 points[3]
Quality of Life				
American Medical Systems Fecal Incontinence Quality of Life Questionnaire[12]	Modification of FIQL[13] Physical impact, Psychological impact, Social impact, Pad use, Lifestyle alterations, Embarrassment/shame, Depression, Coping/Behavior	NR 39 items	NR	
Fecal Incontinence Quality of Life (FIQL)[13]	4 scales(items): Lifestyle (10), Coping/Behavior (9), Depression/Self-Perception (7), Embarrassment (3) *Provides subscale (not overall) score	1-5 per item 29 items	5 (NA)	1.1 to 1.2 points[3] per subscale

Best score= least impaired score possible in scale.

CCFIS=Cleveland Clinic Florida Fecal Incontinence Score; FI=Fecal Incontinence; FIQL=Fecal Incontinence Quality of Life; FISI=Fecal Incontinence Severity Score; GPE=Global Perceived Effect; ICIQ-BS=International Consultation Incontinence Questionnaire Bowel Symptoms; NA=not applicable; NR=not reported; SF-36=Short Form Health Survey

Appendix F. Evidence Tables

Appendix F1. Patient-reported outcomes used in fecal incontinence randomized controlled trials

Measure	Studies in Which Outcome was Used
Severity and Impact of FI and bowel issues	
Ability to safely release gas	Hallgren, 1994[14]
Adequate relief (yes or no)	Heymen, 2009[15]
Appropriate fecal and urine toileting ratio	Schnelle, 2002[16]
Appropriate toileting ratio	Schnelle, 2010[17]
Bowel function	Christensen, 2006[18]
Bowel habits (scale not specified)	Schwander, 2011;[19] Bliss, 2001;[20] Yoshioka, 1999;[21] Palmer, 1980[22]
Bowel movements during day	Hallgren, 1994[14]
Bowel movements over 3 weeks	Duelund-Jakobsen, 2012;[23] Michelsen, 2008[24]
Bowel movements over a mean of 3 days	Kusunoki, 1990[25]
Bowel movements per day	Bartlett, 2011;[26] Schnelle, 2010;[17] Sun, 1997;[27] Hallgren, 1994[14]
Bowel movements per week	Leroi, 2005;[28] Osterberg, 2004;[29] Read, 1982[30]
Bowel openings over 3 weeks	Duelund-Jakobsen, 2013[31]
Bowel symptom questionnaire[32]	Norton, 2003[33]
Browning & Parks Incontinence Score	van Tets, 1998[34]
Cleveland Clinic Constipation Score[35] (0-30)	Christensen, 2006[18]
Cleveland Clinic Fecal Incontinence Score (CCFIS)[2]	Damon, 2014;[36] Duelund-Jakobsen, 2013;[31] Morris, 2013;[37] Duelund-Jakobsen, 2012;[23] Pinedo, 2012;[38] Bartlett, 2011;[26] Graf, 2011;[39]Schwander, 2011;[19] Schwander, 2010;[40] Pinedo, 2009;[41] Tjandra, 2009;[42] Michelsen, 2008;[24] Tjandra, 2008;[43] Naimy, 2007;[44] Healy, 2006;[45] Leroi, 2005;[28] Davis, 2004;[46] Mahoney, 2004;[47] O'Brien, 2004;[48] Hasegawa, 2000;[49] Yoshioka, 1999[21]
Complete fecal continence	Deen, 1993[50]
Complete responders to treatment (percent with no FI for one month)	Schwander, 2011;[19] Schwander, 2010[40]
Duration of bowel management	Coggrave, 2010[51]
Extent of FI (11-point scale, 0-10; 0=best score)	Deen, 1993[50]
Fecal continence grade (I: flatus II: liquid stool III: solid stool)	Schwander, 2011[19]
Fecal soiling (scale not specified)	Yoshioka, 1999[21]
Fecal urgency (ability to reach toilet: "none of the time" "little of the time" "some of the time" "all of the time")	Bartlett, 2011[26]
Fecal urgency (scale not specified)	Leroi, 2005;[28] Yoshioka, 1999[21]
Fecal urgency: days with urgency over 3 weeks	Duelund-Jakobsen, 2013;[31] Duelund-Jakobsen, 2012[23]
Fecal urgency: deferring time (visual analogue scale)	Osterberg, 2004[29]
Fecal urgency: delay for postponing defecation (range: less than 5 minutes to more than 15 minutes)	Leroi, 2005[28]
Fecal urgency: episodes per week	Read, 1982[30]
Fecal urgency: episodes over 3 weeks	Michelsen, 2008[24]
Fecal urgency: stools with urgency over 3 weeks	Duelund-Jakobsen, 2013;[31] Duelund-Jakobsen, 2012[23]
Fecal urgency: rectal urgency (proportion bowel movements preceded by urgency)	Bharucha, 2014[52]
Fecal urgency: time denominator not specified	Sun, 1997[27]
FI episodes: amount ("none" "leakage between buttocks" "on an incontinence absorbent product" "on underwear" "on outerwear" "on shoes/the floor")	Bliss, 2014[53]
FI episodes: change from baseline in number of incontinence-free days	Graf, 2011[39]
FI episodes: days with FI	Bharucha, 2014[52]
FI episodes: days with FI per week	Tjandra, 2008[43]

Measure	Studies in Which Outcome was Used
FI episodes: days with soiling over 3 weeks	Michelsen, 2008[24]
FI episodes: days with staining per week	Tjandra, 2008[43]
FI episodes: days with pads per week	Tjandra, 2008[43]
FI episodes: FI episodes per day	Bharucha, 2014;[52] Bliss, 2014;[53] Schnelle, 2010[17]
FI episodes: FI episodes per week	Tjandra, 2008;[43] Ilnyckyj, 2005;[54] Leroi, 2005;[28] Whitehead, 1985;[55] Read, 1982[30]
FI episodes: FI episodes per 2 weeks	Graf, 2011[39]
FI episodes: FI episodes per 3 weeks	Duelund-Jakobsen, 2013;[31] Michelsen, 2008[24]
FI episodes: FI episodes per month	Deen, 1993[50]
FI episodes: need for night evacuations	Hallgren, 1994[14]
FI episodes: % of daily checks with FI during 1 month	Schnelle, 2002[16]
FI episodes: % incontinent stools over 8 days	Bliss, 2001[20]
FI episodes: % unformed stools per week	Read, 1982[30]
FI episodes: total incontinence over 3 weeks	Duelund-Jakobsen, 2013;[31] Duelund-Jakobsen, 2012[23]
FI episodes: passive incontinence over 3 weeks	Duelund-Jakobsen, 2013;[31] Duelund-Jakobsen, 2012[23]
FI episodes: urgency incontinence over 3 weeks	Duelund-Jakobsen, 2013;[31] Duelund-Jakobsen, 2012[23]
FI episodes: time denominator not specified	Coggrave, 2010;[51] Sun, 1997[27]
FI subscale of Fecal Incontinence and Continence Assessment (FICA)[4]	Bharucha, 2014[52]
Fecal Incontinence Severity Instrument (FISI)[5]	Bharucha, 2014;[52] Heymen, 2009;[15] Lauti, 2008;[56] Park, 2007[57]
Frequency of side effects	Park, 2007[57]
GI Symptom Rating Scale for IBS	Duelund-Jakobsen, 2013;[31] Duelund-Jakobsen, 2012[23]
Impact on daily activities	Christensen, 2006[18]
Improved in grade or frequency of FI (%)	Schwander, 2011;[19] Schwander, 2010[40]
International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF)	Schwander, 2011[19]
Investigator-rated severity (11-point scale, 0-10; 0=no incontinence problems)	Solomon, 2003[58]
Knowles-Eccersley-Scott-Symptom (KESS) questionnaire for constipation	Damon, 2014[36]
Level of stepwise intervention at which evacuation began	Coggrave, 2010[51]
Level of stepwise intervention required to complete evacuation	Coggrave, 2010[51]
Miller's Incontinence Score[7]	Osterberg, 2004[29]
Neurogenic Bowel Dysfunction Score[59]	Christensen, 2006 [18]
Number asymptomatic for FI after therapy	Fynes, 1999[60]
Overall FI symptom score (0-10 per day over 28 days; 0=no symptoms, 280=maximum symptoms)	Carapeti, 2000[61]
Pad days over 3 weeks	Duelund-Jakobsen, 2013;[31] Duelund-Jakobsen, 2012[23]
Pad use (yes or no)	Osterberg, 2004[29]
Pad use: during daytime	Hallgren, 1994[14]
Pad use: during nighttime	Hallgren, 1994[14]
Patient-rated achievement of therapeutic goals (6-point scale; 1=very good, 6=unsatisfactory)	Schwander, 2011[19]
Patient assessment of improvement ("good" "fair" "poor")	Yoshioka, 1999[21]
Patient-rated bowel control (11-point scale, 0-10; 0=no control)	Bartlett, 2011;[26] Norton, 2006[62]
Patient-rated effect of symptoms on life (4-point scale; "not at all" "a little" "quite a lot" "a great deal")	Norton, 2006[62]
Patient-rated effect of treatment (11-point scale, 0-10; 0=no effect)	Naimy, 2007[44]
Patient-rated improvement (estimated percent of overall improvement or deteriorating of symptoms during treatment)	Carapeti, 2000;[61] Carapeti, 2000[63]

Measure	Studies in Which Outcome was Used
Patient-rated severity (11-point scale, 0-10; 0=no incontinence problems)	Solomon, 2003[58]
Patient-rated symptom change (11-point scale, -5 to +5; -5=significant aggravation, +5=significant improvement)	Norton, 2006[62]
Patient-rated treatment effectiveness (“worse” “same” “improved” “cured”) and rating of this change (11-point scale, -5 to +5; -5=significant aggravation, +5=significant improvement)	Damon, 2014;[36] Norton, 2003[33]
Patient satisfaction (100mm visual analogue scale; “not at all” – “completely satisfied”)	Bharucha, 2014[52]
Patient satisfaction (11-point scale, 0-10; 0=very dissatisfied	Norton, 2006;[62] Davis, 2004[46]
Patient satisfaction (11-point scale, 0-10; 0=excellent function)	Duelund-Jakobsen, 2013;[31] Duelund-Jakobsen, 2012[23]
Perianal skin trouble (yes or no)	Kusunoki, 1990[25]
Pescatori Fecal Incontinence Score[8]	Solomon, 2003;[58] Fynes, 1999[60]
Response to treatment (reduction in number of episodes across 2 weeks by 50% or more)	Graf, 2011[39]
Severity of abdominal pain: VAS (100mm; 0=absent)	Sun, 1997[27]
Severity of diarrhea: VAS (100mm; 0=absent)	Sun, 1997[27]
Severity of FI urgency: VAS (100mm; 0=absent)	Sun, 1997[27]
Severity of FI (authors’ own calculation)	Bliss, 2014[53]
Severity of FI: VAS (100mm; 0=absent)	Sun, 1997[27]
Severity of FI urgency (“mild” “moderate” “severe”)	Sun, 1997[27]
Severity of FI urgency: VAS (100mm; 0=absent)	Sun, 1997[27]
Severity of side effects	Park, 2007[57]
Side effects	Palmer, 1980[22]
Soiling (yes or no)	Kusunoki, 1990[25]
Soiling days over 3 weeks	Duelund-Jakobsen, 2013;[31] Duelund-Jakobsen, 2012[23]
Soiling during daytime	Hallgren, 1994[14]
Soiling during nighttime	Hallgren, 1994[14]
St. Mark’s Fecal Incontinence Score (0-13)[9]	Solomon, 2003[58]
Stool consistency (“formed” or “unformed”)	Sun, 1997[27]
Stool consistency (”liquid” “uniformed/loose” “soft/formed” or “hard/formed”)	Bliss, 2001[20]
Stool consistency (“solid” “loose” or “watery”)	Palmer, 1980[22]
Time to stool	Coggrave, 2010[51]
Vaizey Incontinence Score[10]	Dehli, 2013;[64]* Duelund-Jakobsen, 2013;[31]* Bols, 2012;[65] Duelund-Jakobsen, 2012;[23]* Schwander, 2011;[19] Schwander, 2010;[40] Christensen, 2006;[18] Michelsen, 2008;[24]* Carapeti, 2000;[61] Carapeti, 2000[63]
Quality of Life	
American Medical Systems Quality of Life Scale (AMS QoL; 39-items)[12]	O’Brien, 2004[48]
Quality of Life Measure for individually-selected objectives (11-point scale, 0-10; 0=no QoL, 10= full QoL)	Solomon, 2003[58]
Euro-QoL 5D (EQ-5D)	Dehli 2013[64]
Fecal Incontinence Quality of Life (FIQL)[13]	Bharucha, 2014;[52] Damon, 2014;[36] Leroi, 2005;[28] Duelund-Jakobsen, 2013;[31] Bols, 2012;[65] Duelund-Jakobsen, 2012;[23] Pinedo, 2012;[38] Bartlett, 2011;[26] Graf, 2011;[39] Schwander, 2011;[19] Schwander, 2010;[40] Heymen, 2009;[15] Pinedo, 2009;[41] Tjandra, 2009;[42] Lauti, 2008;[56] Tjandra, 2008;[43] Naimy, 2007;[44] Park, 2007;[57] Christensen, 2006[18] (modified); Davis, 2004;[46] Mahoney, 2004[47]

Measure	Studies in Which Outcome was Used
Reduced quality of life (11-point scale, 0-10; 0=normal)	Naimy, 2007[44]
Unpublished FI-specific quality of life measure	Norton 2003[33]
Health Status	
Physical handicap (yes or no)	Osterberg, 2004[29]
Medical Outcomes Survey 36-item health survey (SF-36)[66]	Morris, 2013;[37] Lauti, 2008;[56] Healy, 2006;[45] O'Brien, 2004;[48] Norton, 2003[33]
Medical Outcomes Survey 12-item health survey (SF-12)	Damon, 2014;[36] Tjandra, 2009;[42] Tjandra, 2008[43]
Social handicap (yes or no)	Osterberg, 2004[29]
Other	
Antidiarrheal medication use (type, dosages)	Bliss, 2001[20]
Attitudes Towards Treatment (ATT)	Heymen, 2009[15]
Beck Depression Inventory (BDI)	Heymen, 2009;[15] O'Brien, 2004[48]
Capsule consumption	Palmer, 1980[22]
Dietary intake	Bliss, 2001[20]
Global efficacy question (scale NR)	Park, 2007[57]
Global Perceived Effect (GPE; scale 1-9)	Bols, 2012[65]
Hospital Anxiety and Depression Scale (HAD)	Norton, 2003;[33] Carapeti 2000[63]
Loperamide use (% days)	Bharucha, 2014[52]
Medication use: stool regulation	Schwander, 2011[19]
Satisfaction with treatment	Christensen, 2006[18]
Spielberger State-Trait Anxiety Inventory (STAI-1 and STAI-2)	Heymen, 2009[15]

*Article states St. Mark's Fecal Incontinence Score was used; however, authors cited Vaizey, 1999[10]

Appendix F2. Key Question 1: Fecal incontinence randomized controlled trial outcomes overview by treatment and followup duration

Treatment	Author, year	FI etiology	Followup*	FI count	CCFIS	FISI	Vaizey	FIQL	Inter-mediate	Other
Nonsurgical										
Dietary fiber	Bliss, 2014[53]	NR	ST	X				X	X	FI amount and severity
Dietary fiber	Bliss, 2001[20]	NR	ST	X						Stool freq and consistency, antidiarrheal use, diet
Fiber + loperamide	Lauti, 2008[56]	Mixed	ST, IT			X		X		SF-36
Topical phenylephrine	Park, 2007[57]	Structural	ST			X		X		Side effects freq and severity, global efficacy question
Topical phenylephrine	Carapeti, 2000[63]	NR	ST				X		X	HAD, pt-rated improvement
Topical phenylephrine	Carapeti, 2000[61]	Structural	ST				X		X	Overall FI symptoms score, pt-rated improvement
Loperamide	Sun, 1997[27]	Mixed	ST	X					X	Stool freq; FI urgency, amount, severity; diarrhea, abdominal pain
Loperamide	Hallgren, 1994[14]	Structural	ST	X					X	Defecation freq, need for night evacuation, soiling, pad use, safe gas release
Loperamide	Read, 1982[30]	Mixed	ST	X					X	Stool freq, urgency episodes, unformed stools
Mixed antidiarrheal drugs	Palmer, 1980[22]	Mixed	ST	X						Stool freq, consistency, urgency, capsule consumption
Clonidine	Bharucha, 2014[52]	Mixed	ST	X		X		X	X	FICA, rectal urgency, pt satisfaction, loperamide use
Topical zinc-aluminum ointment	Pinedo, 2012[38]	NR	ST		X			X		
Topical estrogen	Pinedo, 2009[41]	Structural	ST		X			X		
Sodium valproate	Kusunoki, 1990[25]	Structural	ST						X	Stool freq, perianal skin trouble, soiling
PFMT-BF	Damon, 2014[36]	Mixed	IT		X			X	X	KESS, SF-12, pt-rated change and treatment effectiveness
PFMT-BF	Norton, 2003[33]	Mixed	LT						X	SF-36, HAD, bowel symptom questionnaire, pt-rated change and treatment effectiveness, unpublished FI-specific QoL measure
PFMT-BF	Heymen, 2009[15]	Mixed	IT, LT			X		X		Adequate relief, ATT, BDI, STAI-1, STAI-2
PFMT-BF	Whitehead, 1985[55]	Mixed	ST, LT	X					X	
PFMT-BF	Ilnyckyj, 2005[54]	NR	ST	X					X	

Treatment	Author, year	FI etiology	Followup*	FI count	CCFIS	FISI	Vaizey	FIQL	Inter-mediate	Other
PFMT-BF	Bols, 2012[65]	Mixed	ST				X	X	X	GPE
PFMT-BF	Solomon, 2003[58]	Neurogenic	IT						X	SMFIS, Pescatori, investigator- and pt-rated severity, QoL measure for personal goals
PFMT-BF exercise	Bartlett, 2011[26]	Mixed			X			X	X	Bowel movements per day, urgency, pt-rated bowel control
PFMT-BF estim	Schwandner, 2011[19]	Mixed	IT, LT		X		X	X	X	ICIQ-SF, stool freq, % complete responders, FI grade, % improved in FI, goal achievement, medications
PFMT-BF estim	Schwandner, 2010[40]	Mixed	LT		X		X	X		Complete responders to treatment, improved in grade or freq of FI
PFMT-BF +/- estim	Naimey, 2007[44]	Structural	ST		X			X		Pt-rated effect of treatment, reduced QoL
PFMT-BF +/- estim	Mahoney, 2004[47]	Mixed	IT		X			X	X	
PFMT-BF +/- estim	Fynes, 1999[60]	Structural	IT						X	Pescatori, number asymptomatic
Electrostimulation	Norton, 2006[62]	Mixed	ST						X	Pt-rated: bowel control, effect on life, symptom change; pt satisfaction
Electrostimulation	Healy, 2006[45]	NR	IT		X				X	SF-36
Transanal irrigation	Christensen, 2006[18]	Neurogenic	ST				X	X		CCCS, bowel function, impact on daily activities, NBDS, treatment satisfaction
Stepwise bowel management intervention	Coggrave, 2010[51]	Spinal cord injury	ST	X						Duration and level of intervention, time to stool, minimum effective intervention
Exercise + diet	Schnelle, 2010[17]	NR	ST						X	Bowel movements, appropriate toileting ratio
Exercise + incontinence care	Schnelle, 2002[16]	NR	ST, LT	X						Appropriate fecal and urine toileting ratio
Dextranomer	Dehli, 2013[64]	Mixed	IT, LT				X		X	EQ-5D
Dextranomer	Graf, 2011[39]	Mixed	IT, LT	X	X			X		AE, response to treatment
Durasphere**	Morris, 2013[37]	NR	ST, LT		X				X	SF-36
Durasphere**	Tjandra, 2009[42]	Mixed	ST, LT		X			X	X	SF-12
Surgical										
Anal sphincter repair +/- BF	Davis, 2004[46]	Structural	IT, LT		X			X	X	Pt satisfaction
Anal sphincter repair	Hasegewa,	Structural	LT		X				X	

Treatment	Author, year	FI etiology	Followup*	FI count	CCFIS	FISI	Vaizey	FIQL	Inter-mediate	Other
	2000[49]									
Artificial bowel sphincter	O'Brien, 2004[48]	Mixed	IT, LT		X				X	AMS QoL, SF-36, BDI
Gluteus maximus transposition vs. total pelvic floor repair	Yoshioka, 1999[21]	Neurogenic	LT		X				X	Bowel habits, fecal soiling, fecal urgency, pt-assessed improvement
Anterior levatorplasty vs. overlapping sphincteroplasty	Osterberg, 2004[29]	Neurogenic	IT, LT							Miller, stool freq, deferring time, pad use, physical and social handicap
Total pelvic floor repair vs. postanal repair	van Tets, 1998[34]	Neurogenic	IT						X	Browning & Parks Incontinence Score
Total pelvic floor repair vs. anterior levatorplasty vs. postanal repair	Deen, 1993[50]	Neurogenic	LT	X					X	Complete continence, extent of FI
SNS	Duelund-Jakobsen, 2013[31]	Mixed	ST	X	X		X	X	X	GSRS-IBS, bowel openings, days and stools with urgency, pad use, satisfaction, soiling days
SNS	Duelund-Jakobsen, 2012[23]	Mixed	IT	X	X		X	X	X	GSRS-IBS, bowel movements, days and stools with urgency, pad days, pt satisfaction, soiling days
SNS	Tjandra, 2008[43]	Mixed	IT, LT	X	X			X	X	SF-12
SNS	Michelsen, 2008[24]	Mixed	ST	X	X		X			Stool freq, episodes with urgency
SNS	Leroi, 2005[28]	Mixed	ST	X	X			X	X	Bowel movements, urgency, delay for postponing defecation
TOTAL	**49**			**18**	**21**	**4**	**10**	**22**	**34**	

*Followup length: ST= <3 mo; IT= 3 mo-6 mo; LT= >6 mo **Off-label & only 1 arm (Durasphere) was FDA approved

+/-=with or without; AE=Adverse Effects; AMS=American Medical System; ATT=Attitudes Towards Treatment; BDI=Beck Depression Inventory; BF=biofeedback; CCCS=Cleveland Clinic Constipation Score; CCFIS=Cleveland Clinic Fecal Incontinence Score; EQ-5D=EuroQoL Questionnaire-5 Dimensions; estim=electrostimulation; FDA=Food and Drug Administration; FI=Fecal incontinence; FICA=Fecal Incontinence and Continence Assessment; FIQL=Fecal Incontinence Quality of Life; FISI=Fecal Incontinence Severity Index; freq=frequency; FU=Followup; GSRS-IBS=Gastrointestinal Symptom Rating Scale for Irritable Bowel Syndrome; HAD=Hospital Anxiety and Depression Scale; IBS=irritable bowel syndrome; IT=intermediate-term; KESS= Knowles-Eccersley-Scott-Symptom questionnaire for constipation; LT=long-term; Miller=Miller's Incontinence Score; mo=month; NBDS=neurogenic bowel dysfunction score; Pescatori=Pescatori Fecal Incontinence Score; PFMT=Pelvic floor muscle training; pt=patient; QoL=Quality of Life; SNS=Sacral neurostimulation; SF-12=MOS Short-Form 12-item Health Survey; SF-36=MOS Short-Form 36-item Health Survey; SMFIS=St. Mark's Fecal Incontinence Score; SNS=sacral nerve stimulation; ST=short-term; STAI=State-Trait Anxiety Inventory; Vaizey=Vaizey Incontinence Score; VAS=Visual Analogue Scale

Appendix F3. Key Question 1: Distribution of treatments by FI etiology in randomized controlled trials

Treatments	Structural	Neurogenic	Mixed	Unknown or Not Reported	Row Total
Nonsurgical					
Dietary fiber supplements				2[20,53]	2
Antidiarrheal drug plus fiber supplement			1[56]		1
Topical phenylephrine (sphincter function enhancement drug)	2[57,61]			1[63]	3
Antidiarrheal drugs	1[14]		3[22,27,30]		4
Other drugs	2[25,41]		1[52]	1[38]	4
PFMT+/- biofeedback		1[58]	6[15,26,33,36,55,65]	1[54]	8
PFMT-BF +/- electrostimulation	2[44,60]		3[19,40,47]		5
Electrostimulation			1[62]	1[45]	2
Rectal irrigation		1 SCI[18]			1
Multicomponent intervention		1 SCI[51]		2 NH[16,17]	3
Tissue-bulking injections			3[39,42,64]*	1[37]*	4*
Surgical					
Anal sphincter repair (sphincteroplasty)	1[49]				1
Anal sphincter repair +/- Biofeedback	1[46]				1
Anal sphincter replacement		1[21]	1[48]		2
Other surgeries		2[34,50]			2
Surgery vs. nonsurgical treatment				1[29]	1
Sacral neurostimulation			5[23,24,28,31,43]		5
Column Total	9	6	24	10	49

+/-=with or without; BF= biofeedback; NH=nursing home residents; PFMT=pelvic floor muscle training; SCI=adults with spinal cord injury

* Only 1 arm was FDA-approved (off-label Durasphere)

Appendix F4. Key Question 1: Surgical treatments for fecal incontinence: randomized controlled trials and quality ratings

Author, Year	**Study Aim**	**N randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration**	**Study Groups** (n per group)	**Patient-Reported Outcomes** (primary outcome **bolded** if known)	**Reported Results (benefits)***	**Risk of Bias (inverse of quality)**
Anal sphincter repair						
Davis, 2004[46]	Is adjuvant biofeedback after anal sphincter repair superior to sphincter repair alone?	N=38 n=31 100% F: 60 y Structural T: surgery; BF duration NR FU: 3mo, 6mo, 1 y	**T**: Anal sphincter repair + adjuvant biofeedback starting 3 mo post-surgery (18) **C**: Anal sphincter repair (20)	**CCFIS, patient satisfaction**, FIQL	At 1 y post-surgery (9 mo. after BF initiation), differences in change in CCFIS (-5.8 points treated vs. -4.1 points control), pt. satisfaction and FIQL component scores were not significant. Overall FIQL not reported. Power not reported.	High
Hasegawa, 2000[49]	Is anal sphincter repair with fecal diversion superior to sphincter repair?	N=27 n=27 96% F; 46 y Mixed T: surgery FU: mean 34mo	**T**: Anal sphincter repair + stoma (fecal diversion) (13) **C**: Anal sphincter repair (14)	**CCFIS**	Statistical test of difference in scores at followup only: mean CCFIS improved 5.7 points in stoma group vs. 4.4 in controls. Power not reported. Trial stopped early due to high rate of complications, and no treatment advantage	High
Anal sphincter replacement						
O'Brien, 2004[48]	Effectiveness of artificial bowel sphincter (ABS) vs. conservative management for severe FI	N=14 n=13 93% F; 63 y Mixed T: surgery FU: 3 mo, 6 mo	**T**: Artificial Bowel Sphincter (Action Neo-sphincter®) (7) **C**: Conservative medical management (7)	**CCFIS**, SF-36, AMS QoL scale, BDI	Statistical test is of difference in scores at followup not change from baseline. Excluding one patient with a surgical failure that required colostomy and two colostomy revisions, greater CCFIS improvement noted in treated vs. controls at 6 mo (14 vs. 3 points); 3 mo not reported. Significant improvement in AMS-QoL, SF-36 (mental) with surgery; no difference in BDI, SF-36 (physical). Underpowered study.	High
Other surgeries						
Yoshioka, 1999[21]	Compare total pelvic floor repair (TPFR) vs. gluteus maximus (GMT) transposition (without e-stim) (GMT) for postobstetric neuropathic FI	N=24 n=24 100% F; 60 y Obstetric: intact sphincter T: surgery FU: 18 mo.	**T_1**: Total pelvic floor repair (TPFR) (12) **T_2**: GMT without electrical stimulation (12)	CCFIS, self-rated improvement, bowel habit, rectal evacuation, fecal urgency, fecal soiling	Within-group analysis at 18 mo: Same CCFIS improvement (6.1 points) and "good" functional result rating (7 of 12 patients) both groups. No difference in bowel habit, urgency or soiling by group. No power calculation. Authors report limited experience with GMT.	Moderate

Author, Year	**Study Aim**	**N randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration**	**Study Groups** (n per group)	**Patient-Reported Outcomes** (primary outcome **bolded** if known)	**Reported Results (benefits)***	**Risk of Bias (inverse of quality)**
van Tets, 1998[34]	Effectiveness of postanal repair vs. total pelvic floor repair (TPFR) for neurogenic FI	N=20 n=20 100% F; 55 y Neurogenic T: surgery FU: 3 mo	T_1: Postanal repair (11) T_2: Total pelvic floor repair (TPFR) (9)	Browning & Parks Incontinence Score	At 3 mo, 45% in postanal repair group reported improvement vs. 33% in TPFR group. No statistical comparison of patient-reported outcome measure. Power not reported.	Moderate
Deen, 1993[50]	Compare effectiveness of total pelvic floor repair (TPFR) vs anterior levatorplasy vs. postanal repair for neurogenic FI	N=36 n=20 100% F; 51 y Neurogenic T: surgery FU: 6 mo, 2 y	T_1: Total pelvic floor repair (TPFR) (12) T_2: Anterior levatorplasty (12) C: Postanal repair (12)	Complete Continence, FI freq per month extent of FI (0-10)	33% in anterior levatorplasty & 42% in postanal repair reported complete continence. Multiple between-group comparisons reported. FI freq not reported at 6 mo. At 2 y, median (range) FI freq per month was 2 (0-12) for TPFR, 5 (0-30) for anterior levatorplasty, and 10 (0-30) for postanal repair; only comparisons reported are of scores at followup and not of differences from baseline. Data on degree of FI not usable. Power not reported.	High
Surgical vs nonsurgical						
Osterberg, 2004[29]	Compare levatorplasty vs. anal plug electro-stimulation for neurogenic FI	N=70 n=59 88% F; 66 y neurogenic T: 1 d-5 wk FU: 3 m, 1 y, 2 y after treatment completion	T_1: Anterior levatorplasty (31) T_2: Anal plug electrostimulation: 12 sessions (20 min each) with therapist over 4-5 weeks. (28)	Miller's Incontinence score (0-18), stool freq, pad use, physical & social handicap, deferring time	No statistical comparison of between group differences at any time point for any outcome (has within group change from baseline only). Miller's Incontinence score improved 6-7 points with surgery, which was 2-2.5 points more than anal plug e-stim improvements at 3 m, 1 y and 2 y. No change in stool freq. at any time point in either group. Pad use decreased in both groups; physical and social handicap and deferring times improved with surgery. Underpowered study.	High
Surgically-implanted sacral neurostimulation (SNS)						
Duelund-Jakobsen, 2013[31]	Determine whether stimulation at 75% and 50% of the sensory threshold (ST) is	N=19 n=19 95% F; 60 y Mixed T: 1 mo FU:1 mo	Crossover. Wash-out wk 1 of 4 wk trmt T_1: Stimulation at ST (19) T_2: Stimulation at	FI freq, bowel habits, CCFIS, Vaizey, GSRS-IBS, FIQL, patient satisfaction	Improvement in mean FI freq. did not differ significantly across ST settings. Mean change in CCFIS, Vaizey score, bowel habits, GI symptom rating scale for IBS, and pt satisfaction did not differ significantly across settings. Coping	Moderate

Author, Year	Study Aim	N randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome **bolded** if known)	Reported Results (benefits)*	Risk of Bias (inverse of quality)
	as effective as stimulation at ST in pts receiving SNS for FI		75% of ST (19) T_3: Stimulation at 50% of ST (19)		subscale of FIQL improved in ST and 50% of ST groups vs 75% of ST over study period, but no additional significant changes in other FIQL subscales. Power not reported.	
Duelund-Jakobsen, 2012[23]	Which of 5 SNS settings restores efficacy in adults with existing SNS and sustained loss of efficacy?	N=15 n=15 % F: NR; 54 y Mixed T: 5 x 4 wks FU: 20 wks; 11 unblinded for 12 more wks at chosen SNS setting	Crossover T_1- T_5: test 5 SNS stimulator settings (4 wks each), then unblinded and observed for 12 more wks) at preferred setting	FIQL, CCFIS, bowel diary with FI episodes, Vaizey, GSRS-IBS, patient satisfaction	Bowel diary scores including FI episodes significantly improved with high-frequency stimulation and low and prolonged pulse width; FIQL embarrassment improved at 2 settings. No significant differences in other outcomes between settings (20 wk). Outcomes at *preferred* SNS setting showed all measures significantly improved except pad use. Improvement sustained at 32 wk (excluding data from 4 subjects). 8 of 11 satisfied with treatment. Sparse sample information; only mean age, years of FI in text.	High
Tjandra, 2008[43]	Is SNS better than best supportive care for FI?	N=120 n=113 (7 failed test SNS) 93% F; 63 y Mixed T: 1 d up to 1 yr FU: 3 m, 6 m, 1 yr	T: SNS (single surgeon) plus 3 stimulator adjust-ments/1 yr. (53) C: Diet, oral bulking agents, PFMT; met with pelvic floor team 12-18x/1 yr	CCFIS, FI episodes, FI days/wk (bowel diary), FIQL, SF-12	Between-group differences in changes from baseline not reported; results are within-group changes from baseline. Significant decrease in mean FI episodes (9.5 to 3.1) and days of FI/wk (3.3 to 1) with SNS. FIQL improved in all domains with SNS. No significant improvement in control group in any outcome. No power calculation; adjusted for multiple comparisons.	Moderate
Michelson, 2008[24]	Does switching off SNS stimulator at night affect FI in adults with existing SNS?	N=20 n=19 95% F; 59 y Mixed T: 3 wks. each FU: 6 wks: outcomes assessed after both periods only	Crossover, no washout T1: SNS on 24 hr/d x 7 d/wk for 3 wks T2: SNS off at night for 3 wks	CCFIS, Vaizey, defecation frequency, urge episodes, liquid + solid episodes, days with soling	No base values reported for any measures. Median CCFIS and Vaizey increased (worse) by 1 point during OFF at night period. Days with soiling increased by 1; urge episodes unchanged. Power not reported.	High

Author, Year	**Study Aim**	**N randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration**	**Study Groups** (n per group)	**Patient-Reported Outcomes** (primary outcome **bolded** if known)	**Reported Results (benefits)***	**Risk of Bias (inverse of quality)**
Leroi, 2005[28]	Effectiveness of SNS with stimulation ON vs. OFF for FI in new SNS recipients	34 pts received SNS but N=27 randomized; n=24 91% F; 57 y Mixed T: 1 mo x 2 FU: 1 mo, 2 mo	Crossover, no washout T_1: Stimulation ON (27) T_2: Stimulation OFF (27)	FI count, CCFIS, FIQL, urgency episodes, postponing defecation, bowel movements	Median improvement in CCFIS 2 points greater in stimulation ON vs OFF at 1 mo, but difference not significant. Authors report statistically significant improvement in median FI count, but data in graph & not usable. No significant changes in urgency episodes, delay in postponing defecation, and number of BM per week between groups at 1 mo. Results for FIQL not reported. Power not reported.	High

*Significant = statistically significant

AE=Adverse Effects; AMS=American Medical System; AM=anal manometry; BDI=Beck Depression Inventory; BM=bowel movement;; CCFIS=Cleveland Clinic Fecal Incontinence Score; C=Comparator/control; d=day; Est=estimated; Estim=Electrostimulation; F=Female; FI= Fecal incontinence; FICA=Fecal Incontinence and Continence Assessment; FIQL=Fecal Incontinence Quality of Life scale; FU=Followup; FDA=Food and Drug Administration; freq=frequency; GI=gastrointestinal; GSRS-IBS=Gastrointestinal Symptom Rating Scale for Irritable Bowel Syndrome; HAD=Hospital Anxiety and Depression Scale; IAS=internal anal sphincter; IBS=irritable bowel syndrome; mo=month; NR=Not Reported; NSD=No Significant Difference; pt=patient; pd=period; analysis; QoL=Quality of Life; SF-12=Short-Form-12 health survey; SF-36=Medical Outcomes Study Short-Form 36-item Health Survey; surg=surgery; T_1=Treatment group 1 T_2=Treatment group 2 T_3=Treatment group 3; Vaizey=Vaizey Fecal Incontinence Score; VAS=Visual Analogue Scale; wk=week; y=year

Appendix F5. Key Question 1. Observational studies* of fecal incontinence treatments with study quality ratings

Author, Year	Study Aim	Prospective or Retrospective	N analyzed; % Female; FI etiology; Followup Duration	Study Groups (n) Treatment Duration	Patient-Reported Outcomes	Reported Results	Risk of Bias
Nonsurgical							
Sze, 2009[67]	Methyl-cellulose + loperamide vs. no treatment	Prospective	N=69 F: 100% NR FU: 3 mo (T), 8 wk (C)	T: Methylcellulose 1-2 tbsp 2x/d + loperamide 1-2 cap 3x/d (59) C: No treatment (10) 3 mo	FI cure rate: Pescatori, pt-rated improvement, FI urgency, pad use, pt-rated function	Significantly higher cure rate in T vs C (T 46% vs C 0). No attrition.	High
Remes-Troche, 2008[68]	Cholesty-ramine + PFMT-BF vs. PFMT-BF	Prospective	N=42 F: 90% Mixed FU: 3 mo, 1 yr	T: Cholestyramine 2 g/d + PFMT-BF (21) C: PFMT-BF (21) PFMT-BF: 2x/wk; reinforced 3x in 1 yr	Stool frequency/wk, FI episodes/ wk	Significant reduction in FI episodes/wk in both T (-2.2) and C (-1) at 3 mo. No attrition.	Moderate
Byrne, 2005[69]	In-person PFMT-BF vs telephone PFMT-BF	Prospective	N=239 F: 90% Mixed FU: 5 mo	T: In-person PFMT-BF (184) C: Telephone PFMT-BF (55) 1 session/mo for 5 mo	SMFIS, Pescatori, FI severity, QoL	Both groups improved but changes not significantly different by groups for SMFIS, Pescatori, or QoL. Overall attrition 27% (T 14% vs C 30%).	Moderate
Loening-Baucke, 1990[70]	PFMT-BF + medical (fiber, loperamide, Metamucil, other) vs. medical	Prospective	N=17 F: 100% Mixed FU: 3 mo, 1 yr	T: 1 hr PFMT-BF session 3x over 3 mo + 1x/d at home + medical (8) C: Medical (9) 3 mo	Soiling frequency	Soiling frequency decreased in both groups at 3 mo (T 50% vs. C 56%) and 1 yr (T 25% vs. C 44%). At 1 yr, 13% T vs. 11% C free of soiling. Attrition NR.	High
van der Hagen, 2012[71]	Rectal irrigation vs non-FDA	Prospective	N=150 F: 59% NR FU: 6 mo	T: Bulking injection – non-FDA (75) C: Irrigation after defecation for 6 mo (75)	CCFIS, Vaizey, FIQL, FI d/wk, pad use, KEA	FI completely resolved in 44% of irrigation group. No change in other outcomes. Attrition was 4% (3/75).	High
Surgical							
Hong, 2014[72]	Best option for failed AS repair: RS vs. ABS vs. SNS	Retrospective	N= 59 F: 97% Mixed FU: 31 mo (3-138 mo)	T_1: RS (33) T_2: ABS (11) T_3: SNS (15)	CCFIS, FIQL	All groups improved; CCFIS change NSD between groups. CCFIS decrease within groups was RS (-6), ABS (-10.1), SNS (-8.5). Between group change in FIQL NSD.	High

Author, Year	Study Aim	Prospective or Retrospective	N analyzed; % Female; FI etiology; Followup Duration	Study Groups (n) Treatment Duration	Patient-Reported Outcomes	Reported Results	Risk of Bias
Wong, 2012[73]	SNS vs. non-FDA	Retrospective	N=28 F: 100% Mixed FU: 22 mo (range 10-28 mo)	T_1: MAS – non-FDA (12) T_2: SNS (16) 12 mo SNS device surveillance	CCFIS, FIQL, deferring time (minutes), urgency	SNS group improved significantly in CCFIS (-3.5) and FIQL (scores NR).	High
Wong, 2011[74]	ABS vs. non-FDA	Retrospective	N=20 F: 100% Mixed FU: 22 mo	T1: MAS - nonFDA (10)- T2: ABS (10)	CCFIS, FIQL	ABS group significantly improved in median CCFIS (-11.5) and FIQL (scores NR).	High
Ratto, 2010[75]	SNS vs. ASR	Retrospective	N=24 F: 100% Mixed FU: 4 mo, 8 mo, 12 mo, annually (6-96 mo)	T_1: sphincteroplasty (14) T_2: SNS (10)	CCFIS, FI episodes/wk	CCFIS scores improved within both T_1 (-8.7) and T_2 (-8.6). NSD between groups.	High
Dudding, 2009[76]	SNS: open vs. per-cutaneous lead placement	Retrospective	N=48 F: 94% NR FU: 51 mo median (22-106 mo)	T_1: open lead (18) T_2: percutaneous lead (30)	Urgency, FI episodes/wk, soiling/wk	Urgency significantly reduced in both T_1 (-1.5) and T_2 (-2). NSD between groups. No change in FI episodes or soiling.	High
Steele, 2006[77]	Sphincteroplasty +/- PFR	Retrospective	N=28 F: 100% Mixed FU: 34 mo (mean)	T: Sphincteroplasty + PFR (17) C: Sphincteroplasty (11)	CCFIS, pt-rated satisfaction	CCFIS significantly worse in T vs C overall (T 14.2 vs C 5.1). NSD between groups. NSD between groups for pt-rated satisfaction.	High
Tan, 2001[78]	ASR: compare incision placement	Retrospective	N=50 F: 100% Obstetric FU: 23 mo (mean)	T_1: Posterior fourchette incision (18) T_2: perineal incision (32)	Modified Pescatori	Modified Pescatori significantly improved in both T_1 (-8.4) and T_2 (-7.4).	Moderate
Osterberg, 2000[79]	Anterior levatorplasty vs. sphincteroplasty	Prospective	N=51 F: 100% Idiopathic FU: 3 mo, 1 yr	T_1: AL (31) T_2: sphincteroplasty (20)	Miller, social and physical handicap	Significant improvements in Miller for both T_1 (-11) and T_2 (-5) at 1 yr. Attrition NR.	High

Author, Year	Study Aim	Prospective or Retrospective	N analyzed; % Female; FI etiology; Followup Duration	Study Groups (n) Treatment Duration	Patient-Reported Outcomes	Reported Results	Risk of Bias
Briel, 1998[80]	ASR: compare surgical approach	Retrospective	N=55 F: 100% Obstetric FU: 2 yr	T_1: direct ASR (24) T_2: anterior ASR (31)	Continence restored (Grade IV to I/II or Grade III to I via Parks)	Continence restored in 63% (15/24) T_1 and 68% (21/31) T_2.	High

*With comparator/control group

+=with; +/-=with and without; ABS=artificial bowel sphincter; AL=anterior levatorplasty; AS=anal sphincter; ASR=anal sphincter repair; BF=biofeedback; C=comparator; cap=capsules; CCFIS=Cleveland Clinic Fecal Incontinence Scale; d=day; EAS=external anal sphincter; F=female; FDA=Food and Drug Administration; FI=fecal incontinence; FIQL=Fecal Incontinence Quality of Life Scale; FU=followup; g=grams; hr=hour; KEA=KEA quality of life questionnaire score; MAS=magnetic anal sphincter; Miller= Miller's Incontinence Score; N=total patients in study; n=patients in study arm; NR=not reported; NSD=No significant difference; Parks=Browning and Parks Incontinence Score; Pescatori=Pescatori Fecal Incontinence Score; PFMT=pelvic floor muscle training; PFR=pelvic floor repair; pt=patient; QoL=quality of life; RS=repeat sphincteroplasty; SD=standard deviation; SF-12=MOS Short-Form 12-item Health Survey; SF-36=MOS Short-Form 36-item Health Survey; SMFIS=St. Mark's Fecal Incontinence Score; SNS=sacral nerve stimulation; UTI=urinary tract infection; T=treatment group; T_1=Treatment group 1; T_2=Treatment group 2; T_3=Treatment group 3; tbsp=tablespoon; Vaizey=Vaizey Fecal Incontinence Score; vs=versus; wk=week; x=repetition; yr=year

Appendix F6. Key Question 2. Adverse effects of nonsurgical treatments for fecal incontinence in randomized controlled trials

Author, Year	Study Aim	N randomized; n analyzed; % Female; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome **bolded** if known)	Reported Harms	Attrition
Temporary Nonsurgical Treatments*						
Dietary fiber						
Bliss, 2014[53] ***Note**: Same sample as Bliss 2011*[81]	Compare fiber supplements	N=206 n=206 F: 74% NR T: 38 d FU: 38 d	T_1: carboxymethy-cellulose (CMC) (53) T_2: gum arabic (50) T_3: psyllium (54) C: placebo (49)	**FI frequency**, amount, consistency, severity; FIQL	Overall: NR T_1: 11% T_2: None T_3: 11% C: None GI symptoms and allergic reaction most common.	8%* T_1: 11% T_2: 2% T_3: 15% C: 4%
Bliss, 2001{Bliss, 2001 #1017	Compare fiber supplements	N=39 n=39 F: 79% NR T: 31 d FU: 31 d	T_1: psyllium (13) T_2: gum arabic (13) C: placebo (13)	% incontinent, stool frequency, stool consistency, dietary intake	No serious AEs reported.	7%* (3/42 withdrew in baseline, unrelated to treatment)
Drugs: Sphincter Function Enhancers						
Park, 2007[57]	Efficacy of 30% phenylephrine gel for FI after low anterior resection for rectal cancer	N=35 n=29 F: 37% Postsurgical T: 4 wk FU: 4 wk	T: 30% topical phenylephrine (17) 2x/day C: placebo 2x/d (12)	FISI, FIQL, Global Efficacy	Overall: 35% nonserious AEs T: 41% nonserious AEs; local allergic dermatitis 29%, headache 12% C: 17% nonserious AEs	Excluded post-randomization data from 17% with poor compliance
Carapeti, 2000[63]	Effectiveness of 10% topical phenylephrine in FI patients with IAS dysfunction	N=36 n=36 F: 61% NR T: 4 wk each FU: 4 wk, 8 wk	Crossover, 1 wk washout T: topical 10% phenylephrine gel (anus) 2x/d (36) C: placebo gel (36)	**Vaizey score**, subjective improvement	Overall: No serious AEs T: 8% nonserious AEs; mild dermatitis (erythema & pruritus) most common C: None	Not reported
Drugs: Antidiarrheals						
Sun, 1997[27]	Effectiveness of loperamide oxide for chronic diarrhea with FI	N=11 n=11 F: 73% Mixed T: 1 wk each FU: 2 wk 4 wk	Crossover, 1wk run-in, washout T: loperamide 8mg/d (11) C: placebo(11)	FI episodes, % fully continent, stool freq/consistency, urgency, FI severity, diarrhea, abdominal pain	Overall: NR T: 55% nonserious AEs C: 27% nonserious AEs Abdominal pain, headache & nausea most common	None

Author, Year	**Study Aim**	**N randomized; n analyzed; % Female; FI Etiology; Treatment and Followup Duration**	**Study Groups** (n per group)	**Patient-Reported Outcomes** (primary outcome **bolded** if known)	**Reported Harms**	**Attrition**
Hallgren, 1994[14]	Effectiveness of loperamide HCl after proctoco-lectomy for ulcerative colitis	N=30 n=28 F: 27% Postsurgical T: 8 d each FU: 15 d, 30 d	Crossover, 1wk run-in, washout T: loperamide HCl 12mg/d (30) C: placebo (30)	Defecation freq, need for night evacuation, FI episodes, use of pads, flatus release	No AEs occurred	7%*
Read, 1982[30]	Effectiveness of loperamide for chronic diarrhea with FI and urgency	N=26 n=26 F; 57% Mixed T: 1 wk each FU: 1 wk, 2 wk	Crossover, washout NR T: loperamide 12mg/d (26) C: placebo (26)	FI episodes; stool freq, weight and consistency; urgency; improvement in FI and urgency	Overall: No serious AEs reported. T: 69% nonserious AEs C: 4% nonserious AEs Constipation, exacerbation of diarrhea, abdominal pain, and nausea & vomiting most common	None
Palmer, 1980[22]	Compare 3 drugs for chronic diarrhea (95% had urgency with FI)	N=30 n=25 F: NR Mixed T: 4 wk each FU: outcomes every 4 wk up to 12 wk	Crossover; used 3 wk data per period T_1: loperamide HCl 2mg/d (30) T_2: codeine phos-phate 45mg/d (30) T_3: diphenoxylate 5mg/d (30)	FI episodes, # of patients with FI, stool freq. and consistency, urgency episodes, dose/capsule consumption	Overall: NR T_1: 22 AEs in 40% of group T_2: 29 AEs in 48% of group T_3: 39 AEs in 48% of group Abdominal pain, vomiting, constipation most common AEs causing withdrawal.	17% AEs caused discontinuation of treatment: T_1: 16%* T_2: 16%* T_3: 20%* Abdominal pain, vomiting, constipation most common in withdrawals. 5 withdrew due to idiopathic diarrhea
Drugs: Other						
Bharucha, 2014[52]	Effectiveness of clonidine vs. placebo in women with FI	N=44 n=44 F: 100% Mixed T: 4 wk FU: 4 wk	T: Clonidine 0.2mg/d (22) C: placebo (22)	**FICA**, FI count, days of FI, FIQL, FISI, satisfaction, rectal urgency, loperamide use	Overall: No serious AEs. T: 86% nonserious AEs C: 32% nonserious AEs Dry mouth, fatigue, light-headedness and drowsiness most common.	4%* T: 4% C: None

Author, Year	**Study Aim**	**N randomized; n analyzed; % Female; FI Etiology; Treatment and Followup Duration**	**Study Groups** (n per group)	**Patient-Reported Outcomes** (primary outcome **bolded** if known)	**Reported Harms**	**Attrition**
Pinedo, 2012[38]	Compare Zn-Al ointment to anal submucosa vs. placebo for FI	N=50 n=44 F: NR NR T: 1 mo FU: 1 mo	T: Zinc-aluminum ointment 3x/d (25) C:placebo(25)	**CCFIS**, FIQL	No AEs occurred	12% * T: 4% C: 20%
Pinedo, 2009[41]	Compare topical estrogen vs. placebo for FI in postmenopausal women	N=36 n=35 F: 100% NR T: 3x/d for 6 wk FU: 6 wk	T: Estrogen cream to anal submucosa (18) C: placebo(18)	**CCFIS,** FIQL	Overall: NR T: 28% nonserious AEs; mild pruritus ani C: None	3%* T: None C: 6%
Kusunoki, 1990[25]	Effectiveness of valproate sodium for FI after ileoanal anastomosis	N=17 n=17 F: 24% Postsurgical T: 1 wk FU: 1 wk	Crossover, 3 d washout T: Valproate sodium 1600mg/d (17) C: placebo (17)	FI count (soiling), stool freq, perianal skin trouble	Overall: No serious AEs reported. T: 47% nonserious AEs; nausea and abdominal pain most common. C: None	None
PFMT with Biofeedback (BF)						
PFMT-BF vs. standard care						
Damon, 2014[36]	Does PFMT-BF plus standard care improve FI outcomes over standard care only?	N=157 n=92-142 (varied per analysis) F: 77% Mixed T: 4 mo FU: 4 mo	T: PFMT-BF (20 sessions) plus standard care (77) C: standard care of laxative, oral bulking agent, loperamide (80)	**Treatment effectiveness** (-5 to 5), CCFIS, FIQL, KESS, SF-12, symptom change	No AEs occurred	10%* T: 13% C: 6%
vs. PFMT with digital rectal feedback (DRF)						
Bols, 2012[65]	Does PFMT-BF with rectal balloon improve FI over PFMT (digital rectal feedback)?	N=80 n=80 (ITT) F: 90% Mixed T: 9 wk FU: 4.5 mo (varied)	12 sessions/9 wk: T: PFMT-BF plus rectal balloon (40) C: PFMT "alone" (with DRF) (40)	**Vaizey** (0-24); FIQL, GPE	No AEs occurred	13% T: 8% C: 18%
Compare exercises						
Bartlett, 2011[26] *rectal balloon*: both	Compare exercises: PFMT-BF (RBT)	N=72 n=69 (2 mo); 53 at 2 yr	5 sessions/8 wk: T: PFMT-BF rapid & sustained	**CCFIS**, FIQL, self-rated improvement	No AEs occurred	2 mo: 4%* T: 3% C: 5%

Author, Year	Study Aim	N randomized; n analyzed; % Female; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome **bolded** if known)	Reported Harms	Attrition
	mixed exercise vs. PFMT-BF (RBT) sustained contraction	F: 74% Mixed T: 5 sessions/2 mo FU: 2 mo, 2 yr	contraction (35) C: PFMT-BF, sustained contraction (37)			2 yr: 26%* T; 29% C: 24%
PFMT-BF with electrostimulation (estim)						
Compare e-stimulation frequencies						
Schwandner, 2011[19]	Does PFMT-BF with medium freq estim improve FI over PFMT-BF with low freq estim)?	N=80 n=80 (ITT) F: 81% Mixed T: 6 mo FU: 3 mo, 6 mo	T: Estim (medium freq) with PFMT-BF (39) C: Estim (low freq.) with PFMT-BF (41)	**CCFIS**, adapted Vaizey (0-24), FIQL, ICIQ-SF, % complete responders	Overall: NR T: None C: 50%; pain during estim most common	3 mo: 9%* T: 5% C: 12% 6 mo: 11%* T: 8% C: 15%
Electrostimulation						
Norton, 2006[62]	Does home-based estim without PFMT improve FI over sham home-based estim?	N=90 n=90 (ITT) F: 90% Idiopathic T: 2 mo FU: 2 mo	T: estim 35Hz 20 min/d x 3 wk, then 40 min/d x 5 wk (47) C: same protocol but 1Hz estim (43)	Symptom change outcome rating, FI counts/w, 0-10 of bowel control & satisfaction, effectiveness	Overall: Discomfort 9%	22% T: 21% C: 23%
Rectal irrigation						
Christensen, 2006[18]	Compare transanal irrigation to best supportive care	N=87 n=79-87 (ITT) F: 29% Spinal cord injury T: 10 wk FU: 10 wk	T: Transanal irrigation 1x/d then every 2 d or less (42) C: bowel care every 2 d, diet, physical activity, laxatives orconstipating drugs (45)	**CCCS**, **Vaizey** ("SMFIS"), modified FIQL, neurogenic bowel dysfunction score; satisfaction, bowel function, daily activities	Overall: NR T: Bursts of rectal balloon during irrigation (24%*; reported as occurring in 1 in every 3 patients); abdominal distention (2%), hospitalization for severe abdominal pain from constipation (5%), other AE NR (2%). C: None	14%* T: 25% C: 4% Withdrawals for repeated expulsion of rectal catheter during irrigation (7%); bursts of rectal balloon (2%)
Mixed Nonsurgical						
Coggrave, 2010[51]	Does stepwise intervention improve bowel management & reduce FI over usual care?	N: 68 n: 68 (ITT) F: 34% Spinal cord injury T: 6 wk FU: 6 wk	T: Stepwise intervention (7 steps, least to most invasive) (35) C: Usual bowel management (33)	**Duration and level of intervention required**, FI frequency, time to stool, minimum level of effective intervention	Overall: No serious AEs T: 1% nonserious AE C: None	26%* T: 40% C: 12%

Author, Year	**Study Aim**	**N randomized; n analyzed; % Female; FI Etiology; Treatment and Followup Duration**	**Study Groups** (n per group)	**Patient-Reported Outcomes** (primary outcome **bolded** if known)	**Reported Harms**	**Attrition**
Lauti, 2008[56]	Does fiber supplement and loperamide improve FI over low residue diet and loperamide	N: 63 n: 47 F: 91% Mixed T: 12 wk (6 + 6) FU: 6 wk, 12 wk	Crossover T: balanced fiber diet + fiber supplement + loperamide (32) C: low residue diet + placebo fiber + loperamide (31)	**FISI**, FIQL	No AEs occurred	25% T: 22% C: 29%
Permanent Nonsurgical Treatments*						
Local tissue-bulking injections						
Dehli, 2013[64]	Determine if tissue bulking injections with dextranomer superior to PFMT with biofeedback (plus estim if needed) for FI	N: 126 n: 119 (6 mo) F: 93% Mixed T: 6mo control FU: 6 mo (RCT to 6 mo; observed successes to 2 yr)	T: Dextranomer in hyaluronic acid (4 x 1ml injections to anal submucosa); repeat 1x if needed (64) C: PFMT-BF plus estim if needed x 6 sessions/6 mo (62)	**Vaizey** ("St. Mark's" 0-24), FIQL, EQ-5D	Overall: NR T: 25%; leakage of injected agent, infection, prolonged defecation most common C: 8%; pain using anal probe most common.	3%* T: None C: 5% Withdrew consent after randomization: T: n=2 C: n=4
Graf, 2011[39]	Does anal canal injection of dextranomer in stabilized hyaluronic acid improve FI over sham?	N=206 n=197 (6 mo); 125 (1 yr treated only) F: 89% Mixed T: Injections (1 d); repeat in 1 mo if CCFIS >10 FU: 3 mo, 6 mo; 1 yr for treated group	T: Total of 4-8 ml dextranomer injections in four quadrants of anal submucosa (136) C: Sham injections (no substance injected) (70)	**FI counts/wk (50% or more reduction from baseline**) CCFIS, FIQL, number of FI-free days, decrease in FI episodes	Overall: NR Serious AEs: T: rectal abscess (1%), prostate abscess (1%) C: None Nonserious AEs: T: proctalgia (14%), rectal hemorrhage (7%), diarrhea (5%), constipation (2%), injection site bleeding (5%), rectal discharge (4%), anal pruritus (2%), proctitis (3%), painful defecation (2%), fever (8%), other (16%) C: proctalgia (3%), rectal hemorrhage (1%), diarrhea (4%), injection site bleeding (17%), others (7%)	6 mo: 4% T: 3% C: 7% By 1 yr: T: 8% C: Not followed beyond 6 mo.

Author, Year	Study Aim	N randomized; n analyzed; % Female; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome **bolded** if known)	Reported Harms	Attrition
Off-label & only 1 arm FDA approved						
Morris, 2013[37] injected outpatient surgery	Compare injectable bulking agents: Durasphere® (off-label) vs PTQ™ (not FDA approved)	N=35 n=34 overall F: NR NR T: 1 d FU: 6 wk, 6 mo, 1 yr	T_1: Durasphere®: perianal injection (18) T_2: PTQ™ (not-FDA approved) (17)	**CCFIS**, SF-36	Overall: NR T_1: None T_2: NR	6%
Tjandra, 2009[42]	Compare injectable bulking agents: Durasphere® (off-label) vs. PTQ™ (not FDA approved)	N=40 n=40 overall F: 90% Mixed T: 1 d FU: 2 wk, 6 wk, 6 mo, 1 yr	T_1: Durasphere®: perianal injection (20) T_2: PTQ™ (not-FDA approved) (20)	**CCFIS**, FIQL, SF-12	Overall: NR T_1: Serious AEs: rectal pain, erosion through rectal mucosa, hypersensitivity reaction (required hospital-ization & IV steroids). Nonserious AEs: bruising. T_2: NR	None

**Attrition based on the number randomized. Attrition (n, %) was calculated by the MN EPC when study authors reported attrition only among the subset of patients who completed the study or perfectly completed the protocol.

AE=Adverse Effects; AMS=American Medical System; AM: anal manometry; BDI=Beck Depression Inventory; BM=bowel movement; CCCS: Cleveland Clinic Constipation Score; CCFIS=Cleveland Clinic Fecal Incontinence Score; C=Comparator/control ; d=day; dx=diagnosis; DRF: digital rectal feedback; DYS=Dysfunctional; E-diary=Electronic diary; EQ-5D=EuroQoL Questionnaire-5 Dimensions; F=Female; FI=Fecal incontinence; FICA=Fecal Incontinence and Continence Assessment; FIQL=Fecal Incontinence Quality of Life scale; FISI=Fecal Incontinence Severity Index; FU=Followup; FDA=Food and Drug Administration; freq=frequency; GI=gastrointestinal; g=Grams; HAD: Hospital Anxiety and Depression Scale; IAS=internal anal sphincter; IBS=irritable bowel syndrome; ITT=Intention-to-treat analysis; M=Male; mo=month; mg=milligrams; ms=microseconds; neurogenic bowel dysfunction score (NBDS); NR=Not Reported; NSD=No Significant Difference; pt=patient; PFMT=Pelvic floor muscle training; pd=period; PP=Per protocol analysis; PTQ™=injectable bulking agent not FDA approved for use in the US; QoL=Quality of Life; reps: repetitions; SMFIS: St. Mark's Fecal Incontinence Score; s=Seconds; SAE=Serious Adverse Event; SF-12=Short-Form-12 health survey; SF-36=Medical Outcomes Study Short-Form 36-item Health Survey; surg=surgery; T_1=Treatment group 1 T_2=Treatment group 2 T_3=Treatment group 3; TEAE=Treatment Emergent Adverse Event; Vaizey=Vaizey Fecal Incontinence Score; VAS=Visual Analogue Scale; wk=week; y=year

Appendix F7. Key Question 2: Adverse effects of treatments for fecal incontinence in observational studies with comparison groups

Author, Year	Study Aim	Prospective or Retrospective	N analyzed; % Female; FI etiology; Followup Duration	Study Groups (n) Treatment Duration	Patient-reported Outcomes	Reported Harms	Attrition
Nonsurgical							
Sze, 2009[67]	Methyl-cellulose + loperamide vs. no treatment	Prospective	N=69 F: 100% NR FU: 3 mo (T), 8 wk (C)	T: Methylcellulose 1-2 tbsp 2x/d + loperamide 1-2 cap 3x/d (59) C: No treatment (10) 3 mo	FI cure rate: Pescatori, pt-rated improvement, FI urgency, pad use, pt-rated function	Overall: 5% (3/59) T: constipation and abdominal cramps	None
Remes-Troche, 2008[68]	Cholesty-ramine + PFMT-BF vs. PFMT-BF	Prospective	N=42 F: 90% Mixed FU: 3 mo, 1 yr	T: Cholestyramine 2 g/d + PFMT-BF (21) C: PFMT-BF (21) PFMT-BF: 2x/wk; reinforced 3x in 1 yr	Stool frequency/wk, FI episodes/ wk	Overall: 33% Constipation, excessive gas, abdominal bloating, headache most common	None
van der Hagen, 2012[71]	Rectal irrigation vs non-FDA	Prospective	N=150 F: 59% NR FU: 6 mo	T: Bulking injection – non-FDA (75) C: Irrigation for 6 mo (75)	CCFIS, Vaizey, FIQL, FI d/wk, pad use, KEA	None occurred with irrigation	4% (3/75)
Surgical							
Hong, 2014[72]	Best option for failed AS repair: RS vs. ABS vs. SNS	Retrospective	N= 59 F: 97% Mixed FU: 31 mo (3-138 mo)	T_1: RS (33) T_2: ABS (11) T_3: SNS (15)	CCFIS, FIQL	Overall: 36%; wound infection most common: ABS: 73% , RS: 24% SNS: 33%; Reoperation for device removal: ABS: 55%, SNS: 40%	NA
Wong, 2012[73]	SNS vs. non-FDA	Retrospective	N=28 F: 100% Mixed FU: 22 mo (10-28 mo)	T_1: MAS – non-FDA (12) T_2: SNS (16)	CCFIS, FIQL, deferring time (minutes), urgency	2 AEs: 1 patient (6%) had device removed for infection 1 yr after implantation; 1 patient had occasional constipation.	NA
Wong, 2011[74]	ABS vs. non-FDA	Retrospective	N=20 F: 100% Mixed FU: 22 mo	T1: MAS – non-FDA (10) T2: ABS (10)	CCFIS, FIQL	Serious AEs in 40% (4/10): 4 needed revisions (3 leakage from anal cuff, 1 pressure-regulating balloon); of these 1 infection, 1 severe pain.	NA
Dudding, 2009[76]	SNS	Retrospective	N=48 F: 94% NR FU: 51 mo	T_1: open lead (18) T_2: percutaneous lead (30)	Urgency, FI episodes/wk, soiling/wk	Serious AEs in 6% (3/48): T_1: 2 wound infections T_2: 1 lead dislocation requiring surgery	NA

Author, Year	Study Aim	Prospective or Retrospective	N analyzed; % Female; FI etiology; Followup Duration	Study Groups (n) Treatment Duration	Patient-reported Outcomes	Reported Harms	Attrition
			median (22-106 mo)				
Steele, 2006[77]	Sphincteroplasty +/- PFR	Retrospective	N=28 F: 100% Mixed FU: 34 mo (mean)	T: Sphincteroplasty + PFR (17) C: Sphincteroplasty (11)	CCFIS, pt-rated satisfaction	Overall: 43% serious AEs; 39% required further surgery. T: 47%: wound separation (7), infection (2), abscess (1), stenosis (2), impaction (1), and urinary retention (3) C: 36%: wound separation (5), infection (1), abscess (1)	NA
Tan, 2001[78]	ASR: compare incision placement	Retrospective	N=50 F: 100% Obstetric FU: 23 mo (mean)	T_1: Posterior fourchette incision (18) T_2: perineal incision (32)	Modified Pescatori	Wound complications: T_1 11%, T_2 44% ; Wound breakdown: T_1 6%, T_2 16%	NA
Osterberg, 2000[79]	Anterior levatorplasty vs. sphincteroplasty	Prospective	N=51 F: 100% Idiopathic FU: 3 mo, 1 yr	T_1: AL (31) T_2: sphincteroplasty (20)	Miller, social and physical handicap	Serious AEs in 6% T_1 (2 wound infections)	NR
Briel, 1998[80]	ASR	Retrospective	N=55 F: 100% Obstetric FU: 2 yr	T_1: direct ASR (24) T_2: anterior ASR (31)	Continence restored (via Parks)	11 AEs reported: Wound abscess (T_1 3 vs T_2 2); UTI (T_1 2 vs T_2 0) T_2 other: 1 perineovaginal fistula, 1 rectovaginal fistula, 1 dyspareunia/breakdown	NA

+=with; +/-=with and without; ABS=artificial bowel sphincter; AE=adverse effect; AL=anterior levatorplasty; AS=anal sphincter; ASR=anal sphincter repair (sphincteroplasty); BF=biofeedback; C=comparator; cap=capsules; CCFIS=Cleveland Clinic Fecal Incontinence Scale; d=day; EAS=external anal sphincter; F=female; FDA=Food and Drug Administration; FI=fecal incontinence; FIQL=Fecal Incontinence Quality of Life Scale; FU=followup; g=grams; hr=hour; KEA=KEA quality of life questionnaire score; KQ 2=Key Question 2; MAS=magnetic anal sphincter; Miller= Miller's Incontinence Score; N=total patients in study; n=patients in study arm; NA=not applicable; NR=not reported; NSD=No significant difference; Parks=Browning and Parks Incontinence Score; Pescatori=Pescatori Fecal Incontinence Score; PFMT=pelvic floor muscle training; PFR=pelvic floor repair; pt=patient; QoL=quality of life; RS=repeat sphincteroplasty; SD=standard deviation; SF-12=MOS Short-Form 12-item Health Survey; SF-36=MOS Short-Form 36-item Health Survey; SMFIS=St. Mark's Fecal Incontinence Score; SNS=sacral nerve stimulation; UTI=urinary tract infection; T=treatment group; T_1=Treatment group 1; T_2=Treatment group 2; T_3=Treatment group 3; tbsp=tablespoon; Vaizey=Vaizey Fecal Incontinence Score; vs=versus; wk=week; x=repetition; yr=year

Appendix F8. Key Question 2. Adverse effects of surgical treatments for fecal incontinence in randomized controlled trials

Author, Year	Study Aim	N Randomized; n Analyzed; % Female; FI Etiology; Treatment and Followup	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome bolded)	Reported Harms	Attrition
Surgical Treatments						
Anal sphincter repair						
Hasegawa, 2000[49]	Is anal sphincter repair with fecal diversion superior to sphincter repair?	N=27 n=27 F: 96% Mixed T: surgery FU: mean 34 mo	**T**: Anal sphincter repair + stoma (fecal diversion) (13) **C**: Anal sphincter repair (14)	**CCFIS**	Overall: No nonserious AEs reported. T: 12 serious AEs in 13 patients; wound infection, parastomal hernia, prolapsed stoma, incisional hernia at stoma site. C: 3 serious AEs in 14 patients; wound infection, fistula, fecal impaction. Trial stopped after 3 yrs due to high rate of complications and no treatment advantage in anal sphincter repair + stoma group.	None
Anal sphincter replacement						
O'Brien, 2004[48]	Effectiveness of artificial bowel sphincter (ABS) vs. conservative management for severe FI	N=14 n=13 F: 93% Mixed T: surgery FU: 3 mo, 6 mo	**T**: Artificial Bowel Sphincter (Action Neo-sphincter®) (7) **C**: Conservative medical management (7)	**CCFIS**, SF-36, AMS QoL scale, BDI	Overall: No nonserious AEs reported. Serious AEs: T: 43%; failure of perineal wound healing that required colostomy, prolonged hospital stay, inability to evacuate without assistance, delayed healing of perineal wound that required resuturing C: None	7%* T: 14% C: None
Other surgeries						
Yoshioka, 1999[21]	Total pelvic floor repair (TPFR) vs. gluteus maximus transposition (without electrical stimulation) for post-obstetric neuropathic FI	N=24 n=24 F: 100% Obstetric: intact sphincter T: surgery FU: 18 mo	**T_1**: Total pelvic floor repair (TPFR) (12) **T_2**: GMT without estim (12)	CCFIS, FI improvement bowel habit, rectal evacuation, urgency, soiling	Overall: No nonserious AEs reported. T_1: 8% serious AEs T_2: 25% serious AEs Wound sepsis, wound hematoma, fecal impaction most common.	None
Deen, 1993[50]	Compare total pelvic floor repair (TPFR) vs. anterior levatorplasy vs. postanal repair for neurogenic FI	N=36 n=20 F: 100% Neurogenic T: surgery FU: 6 mo, 2 yr	**T_1**: TPFR (12) **T_2**: Anterior levatorplasty (12) **T_3**: Postanal repair (12)	Complete continence, FI freq, extent of FI (0-10)	AEs during surgery not reported. Serious AEs NR by group: Wound infection (1), iatrogenic incision of anterior wall of anorectum (1). More nonserious AEs with TPFR & anterior levatorplasty vs. postanal repair (42% dyspareunia, 42% dyspareunia vs 0);	None

Author, Year	Study Aim	N Randomized; n Analyzed; % Female; FI Etiology; Treatment and Followup	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome bolded)	Reported Harms	Attrition
Surgical vs nonsurgical						
Osterberg, 2004[29]	Compare levatorplasty vs. anal plug electro-stimulation for neurogenic FI	N=70 n=59 F: 88% Neurogenic T: surgery vs 4 wks (median) FU: 3 mo, 1 yr, 2 yrs	**T_1**: Anterior levatorplasty (31) **T_2**: Anal plug electrostimulation (28)	MISS, stool freq, pad use, physical & social handicap, deferring time	Overall: NR Serious AEs: T: 3%; wound infection C: None Nonserious AEs: T: None C: 9%; pain, burning sensation in vagina most common.	16%* T: 11% C: 20%
Sacral neurostimulation (SNS)						
Tjandra, 2008[43]	Is SNS better than best supportive care for FI?	N=120 n=113 (7 failed SNS test so SNS not implanted) F: 93% (est.) Mixed T: 1 d up to 1 yr FU: 3 mo, 6 mo, 1 yr	**T**: SNS (53) **C**: Diet, oral bulking agents, PFMT; met with pelvic floor team 12-18x/1 yr	CCFIS, bowel diary, FIQL, SF-12	Overall: No serious AEs reported. T: pain at implant site (6%); seroma (2%); vaginal tingling (9%) C: constipation from Immodium (10%)	None
Leroi, 2005[28]	Effectiveness of SNS with stimulation ON vs OFF for FI in new SNS recipients	34 pts received SNS but N=27 randomized; n=24 F: 91% Mixed T: 1 mo x 2 FU: 2 mo: 1 mo x 2	Crossover, no washout **T_1**: Stimulation ON (27) **T_2**: Stimulation OFF (27)	FI count, CCFIS, FIQL, urgency episodes, postponing defecation, bowel movements	NR during trial period. Prior to randomization during implantation period, 4 patients withdrew due to unresolved pain (3) and recurrent infection (1).	10%*

* Attrition calculated by the MN EPC based on the number randomized

ABS=artificial bowel sphincter; AE=adverse effects; AMS=American Medical Systems; BDI=Beck Depression Inventory; C=Comparator ; d=day; CCFIS=Cleveland Clinic Florida Fecal Incontinence Score; est.=estimated; estim=intra-anal electrostimulation; F=Female; FI=Fecal Incontinence; FIQL=Fecal Incontinence Quality of Life Instrument; freq=frequency; FU=followup; GMT=gluteus maximus transposition; IAS=internal anal sphincter; IBS=irritable bowel syndrome; ICIQ-BS=International Consultation Incontinence Questionnaire Bowel Symptoms; MISS=Miller's Incontinence Score System; mo=month; NA=not applicable; NR=not reported; PFMT=pelvic floor muscle training; PP=per protocol analysis; pt=patient; QoL=Quality of Life; SECCA=Radiofrequency anal sphincter remodeling; SF-12=MOS Short-Form 12-item Health Survey; SF-36=MOS Short-Form 36-item Health Survey; SNS=sacral nerve stimulation; T1=Treatment group 1; T2=Treatment group 2; T3=Treatment group 3; TPFR=total pelvic floor repair; wk=week; x=times; yr=year

Appendix F9. Key Question 2. Adverse effects reported in surgical case series of fecal incontinence treatments

Author, Year	Study Aim	Number of Patients % Female Mean Age/Median* FI Etiology Followup (range)	Adverse Effects of Surgical Treatment: Serious, Other
SECCA			
Abbas, 2012[82]	Safety and long-term efficacy of temperature-controlled radiofrequency energy (the SECCA® procedure) for FI at a single institution	N: 27 (31 procedures) 81% 64 yr Mixed 6 mo (3-40)	Serious: None Other: Minor complications in 5 pts (19%), including anal bleeding (15%) and swelling of the vulva (4%).
Ruiz, 2010[83]	Efficacy of the SECCA® procedure at 1 yr followup	N: 24 96% 73 yr (in 16 pts) Mixed 1 yr	Serious: Surgical complication in 3 pts (13%); including postoperative bleeding and diarrhea. Other: Minor complication in 5 pts (21%); including side effects from preparation for procedure in 4 pts (nausea/vomiting, allergic reaction, abscess formation, urinary tract infection), constipation following surgery (1 pt.)
Takahashi-Monroy, 2008[84]	Long-term (5 yr) efficacy and safety of the SECCA® procedure	N: 19 95% 57 yr Mixed 5 yr	Serious: Surgical complications in 6 pts (32%), including delayed bleeding (with 1 pt requiring anoscopy and suture ligation). Other: Authors report no long-term complications observed.
Lefebure, 2008[85]	Efficacy of the SECCA® procedure at a single institution at 1 yr followup	N: 15 93% 53 yr Mixed 1 yr	Serious: None Other: Authors report no immediate surgical or long-term complications observed.
Felt-Bersma, 2007[86]	Efficacy and safety of the SECCA® procedure	N: 11 100% 61 yr Mixed 1 yr	Serious: Authors report no major side effects. 3 pts (27%) experienced pain during procedure. Other: Minor adverse effects occurred in 16 patients; pain, hematoma and/or minor bleeding, and antibiotic-associated diarrhea most common.
Efron, 2003[87]	Efficacy and safety of the SECCA® procedure	N: 50 86% 61 yr Mixed 6 mo	Serious: Surgical complication in 3 pts (6%); including mucosal ulceration (1 superficial, 1 with underlying muscle injury) and delayed bleeding from hemorrhoidal vein required suture ligation. Delayed surgical complication in 1 pt (2%) at 3 mo; stercoral perforation required a colostomy. Other: Mild bleeding during procedure not requiring intervention occurred in 11 pts (22%); 26 minor AE following procedure; antibiotic-associated diarrhea, minor bleeding, pain, and fever not associated with infection most common.
ACE/MACE			
Chereau, 2011[88]	Long-term efficacy of the	N: 75	Serious: Early surgical complications (<3 mo.) in 4 pts (5%); wound infection

Author, Year	Study Aim	Number of Patients % Female Mean Age/Median* FI Etiology Followup (range)	Adverse Effects of Surgical Treatment: Serious, Other
	antegrace colonic enema (ACE) procedure among adults	72% 48 yr (median) Mixed 4 yr (median) (4-110 mo)	and hematoma most common. Late surgical complications (>3 mo.) requiring re-admission in 12 pts (16%); stenosis of stoma, large bowel obstruction, stoma prolapse most common. Recurrent impaction in half of pts who had prior impaction. Other: Minor adverse effects occurred in 11 pts (15%); reflux from stoma, pain most common.
Worsoe, 2008[89]	Long-term efficacy of the ACE alone and ACE combined with colostomy, among adults with FI and/or constipation	N: 80 80% 51 yr Mixed 6.25 yr (mean) (3-183 mo)	Serious: Early surgical complications (<3 mo.) in 19 pts (24%); wound infection, infection, urinary tract infection most common. Late surgical complications (>3 mo.) in 11 pts (15%); stenosis of appendicostomy, perforation most common. Other: Minor adverse effects in 27 pts (63%); autonomous symptoms (chills, nausea), painful catheterization, skin problems or rectal bleeding most common.
Koivusalo, 2008[90]	Efficacy of the ACE procedure for congenital FI in adults	N: 27 66% 19 yr (median) Mixed 25 mo (median) (3-117 mo)	Overall: unclear adverse effects reporting. Serious: Perioperative complications (<1 mo.) in 3 pts (11%); iatrogenic small bowel perforation, posteroperative ileus, pelvic abscess most common. Late surgical complications in 17 pts (63%); peristomal infection, conduit stenosis (at skin level, fascial level), excessive fecal reflux, excess mucosal tissue most common. Re-operation for late complications in 13 pts (48%), totaling 25 additional procedures. Other: Minor adverse events not reported.
Krogh, 1998[91]	Efficacy of the ACE procedure in adults with FI and/or constipation	N: 16 (10 pts with FI) 63% 41 yr Mixed 17 mo (1-39 mo)	Serious: Surgical complications reported in 7 pts (44%); wound infection, stenosis of the appendicostomy most common. In 1 pt with stenosis of stoma, revision required. Other: Minor adverse events in 4 pts (25%); abdominal pain most common.
Sphincter Replacement			
Darnis, 2013[92]	Short- and long-term efficacy and safety of the Acticon® Neosphincter artificial bowel sphincter (ABS)	N: 21 71% 51 yr Mixed 38 mo (12-98 mo)	Serious: All patients experienced at least 1 surgical complication; infection or cutaneous ulceration, perianal pain, and rectal evacuation most common. Explant occurred in 17 pts (81%). Other: Minor adverse effects not reported.
Wong, 2011[93] PMID 22107742	Long-term efficacy and safety of the Acticon® Neosphincter ABS	N: 52 (85 devices) 88% 52 yr Mixed 64 mo (2-169 mo)	Serious: 26 pts (50%) required revision of original surgery, leak due to perforation was most common reason. Explant occurred in 14 pts (27%), infection most common reason. Other: Minor adverse effects not reported.
Michot, 2010[94]	Efficacy of Acticon® Neosphincter ABS with a	N: 32 100%	Serious: Serious complications within 6 mo. of operation in 9 pts (28%) requiring removal of ABS; septic adverse event, poor function, and

Author, Year	Study Aim	Number of Patients % Female Mean Age/Median* FI Etiology Followup (range)	Adverse Effects of Surgical Treatment: Serious, Other
	transvaginal (rather than perineal) approach	63 yr Structural 41 mo (18-75 mo)	psychological problems cited as reasons Other: Minor adverse effects not reported.
Ruiz Carmona, 2009[95]	Long-term efficacy and safety of the Acticon® Neosphincter ABS	N: 17 82% 46 yr Mixed 68 mo (3-133 mo)	Serious: All patients experienced at least 1 surgical complication, and at least 1 reoperation required in 65% of pts; erosion and infection most common. Explant occurred in 11 pts (65%), after which 7 had a new implant. Other: Minor difficulties in rectal emptying in 3 patients (18%).
Melenhorst, 2008[96]	Efficacy of the Acticon® Neosphincter ABS	N: 33 76% NR NR 17 mo (1-106 mo)	Serious: Infection requiring removal of ABS in 7 pts (21%). Perianal pain without infection requiring colostomy in 1 pt (3%). Other: Minor adverse effects in 12 pts (36%); rectal evacuation problems needing conservative management most common.
Casal, 2004[97]	Efficacy of the Acticon® Neosphincter ABS	N: 10 (12 procedures) 80% 56 yr Mixed 29 mo (mean)	Serious: Postoperative complications in 6 pts (60%); abdominal wound, superficial dehiscence of the perianal wound, infection of the perianal wound, perianal hematoma most common. Explant occurred in 3 pts (30%), after which 2 had a new implant. Other: Minor adverse effects not reported.
Parker, 2003[98]	Efficacy of the Acticon® Neosphincter ABS at a single institution Group I: retrospective Group II: prospective	N: 45 60% 44 yr Mixed I: 91mo(29-143 mo) II: 39 (12-60 mo)	Serious: Procedure was unsuccessful in 2 pts (4%). Complications occurred in 16 pts (36%); infection, fluid leak, pain most common. Revision required in 13 pts (29%) and complete device replacement in 7 (16%), for a total of 21 revision procedures. Infections occurred in 19% of revisions. Explant of the ABS occurred in 18 pts (40%). Of these, 9 pts (20%) received stoma. Other: Constipation in 4 pts (9%).
Wong, 2002[12]	Efficacy and safety of the Acticon® Neosphincter ABS	N: 112 (185 procedures) 77% 49 yr Mixed 1 yr	Serious: Total of 384 surgical complications occurred in 99 pts (88%). Of these, 246 required minimal to no intervention. Complications were infections. A total of 73 surgical revisions required in 51 pts (46%). Explant of the ABS in 41 pts (37%), after which 7 had a new ABS implanted. Other: 30 pts (27%) reported constipation; 21 pts (19%) reported impaction.
Ortiz, 2002[99]	Efficacy and safety of the Acticon® Neosphincter ABS	N: 22 (24 procedures) 77% 47 yr Mixed 28 mo (6-48 mo)	Serious: Complications occurred in 17 pts (77%). Postoperative complications in 9 pts (41%); of these, 2 required reoperation due to perineal infection. Long-term complications in 10 pts (45%); of these, 9 required reoperation. Explant of the ABS in 7 pts (32%).

Author, Year	Study Aim	Number of Patients % Female Mean Age/Median* FI Etiology Followup (range)	Adverse Effects of Surgical Treatment: Serious, Other
Davesa, 2002[100]	Efficacy and safety of the Acticon® Neosphincter ABS	N: 53 66% 46 yr Mixed 26.5 mo (7-55 mo)	Serious: Perioperative complications in 14 pts (26%); abnormal bleeding, vaginal perforation, rectal perforation most common. Early complications in 16 pts (30%); sepsis, wound complication most common. Late complications in 29 pts (55%); impaction, cuff and/or pump erosion, pain, infection, mechanical failure most common. Explant occurred in 10 pts (19%). Other: Diarrhea in 4 pts (8%).
Altomare, 2001[101]	Efficacy and safety of the Acticon® Neosphincter ABS	N: 28 100% 58 yr Mixed 19 mo (7-41 mo)	Serious: Complications in 18 pts (64%). Early infection in 4 pts, removal required in 3 of these pts. Dihiscence of perineal wound in 9 pts. Problems with cuff in 5 pts (rectal erosion, anal pain, late infection, malfunction). Explant occurred in 5 pts (18%). Other: Minor AE in 14 pts (50%); obstructed defecation, anal pain most common.
O'Brien, 2000[102]	Efficacy and safety of the Acticon® Neosphincter ABS	N: 13 77% 44 yr (median) Mixed NR	Serious: Perioperative complications in 1 pt (7%); wound infection required removal of device. Late complications in 2 (15%) that required removal of device; late infection and erosion for the skin reasons. Other: Minor adverse effects not reported.
Lehur, 2000[103]	Efficacy and safety of the Acticon® Neosphincter ABS	N: 24 71% 44 yr (median) Mixed 20 mo (10-35 mo)	Serious: Perineal wound dehiscence in 2 pts (8%). Explant occurred in 7 pts (29%), after which 3 had a new implant. Other: Minor adverse effects in 9 pts (38%); minor and major rectal emptying difficulties most common.
Christiansen, 1999[104]	Long-term efficacy and safety of artificial anal sphincter (AAS) [using a urinary sphincter and a modified urinary sphincter]	N: 17 65% 46 yr (median) Mixed 7 yrs (5-10yrs)	Serious: Complications occurred in 7 pts (41%); infection and malfunction most common and explant was required in these 7 pts. 2 pts (12%) died in the first 3 yrs of followup of unrelated causes. Five of 8 pts with functioning AAS after 5 yrs required surgical revision procedures early on. Other: Minor adverse effects in 1 pt (6%); rectal emptying difficulties.
Sphincter Repair			
Oom, 2009[105]	Efficacy of anterior sphincteroplasty (overlapping sphincteroplasty)	N: 172 97% 57 yr Mixed 111 mo (12-207 mo)	Serious: Postoperative complication in 39 pts (23%); wound infection most common, with 21 pts (12%) requiring reoperation. Other complications ileus, deep vein thrombosis, and pulmonary embolism. Other: Minor adverse effects not reported.
Kaiser, 2008[106]	Efficacy of anterior sphincteroplasty among women with cloaca-like deformity from obstetric trauma	N: 12 100% 37 yrs (median) OB 39 mo (mean)	Serious: Postoperative complication in 3 pts (25%); rectovaginal fistula most common. In 1 pt, faecal diversion and bulbocavernosus flap required. Other: Minor infections reported in 8 pts (67%).
Grey, 2007[107]	Report short and long term	N: 85	Serious: Surgical complications in 23 pts (27%); wound infection, urinary tract

Author, Year	Study Aim	Number of Patients % Female Mean Age/Median* FI Etiology Followup (range)	Adverse Effects of Surgical Treatment: Serious, Other
	outcomes from anterior sphincter repair; identify factors in long term success	82% 46 yr Structural 12 yr (mean) (5-12 yr range)	infection, hematoma, fecal impaction, pain most common. Other: Minor adverse effects not reported.
Ha, 2001[108]	Efficacy of overlapping anal sphincter reconstruction	N: 49 (52 procedures) 94% 44 yr Mixed 6 mo	Serious: 13 pts (27%) experienced 15 surgical complications; wound complication, fecal impaction, rectovaginal fistula most common. Other: Minor adverse effects not reported.
Ho, 1999[109]	Efficacy of anterior anal sphincter repair	N: 15 100% 51 yr OB 42 mo (mean)	Serious: Surgical complications in 4 pts (26%); wound infection and two stitch sinuses most common. Repeat anterior sphincter repair in 1 pt (7%). Other: Minor adverse effects not reported.
Sitzler, 1996[110]	Efficacy of anal sphincter repair	N: 31 87% 42 yr Mixed (1-36 mo)	Serious: Complications due to surgical procedure in 6 pts (20%), and 9 pts (32%) experienced morbidity following procedure; wound infection, perineovaginal fistula, chest infection, hernia, stitch sinus, impaction, and prolapse of stoma most common. Other: Minor adverse effects not reported.
Nikiteas, 1996[111]	Efficacy of anal sphincter repair over a 5 yr period	N: 42 76% NR overall Mixed 38 mo (median) (12-66 mo)	Serious: Surgical complications in 2 pts (5%); breakdown of sphincter repair due to sepsis most common. Both pts required reoperation. Other: Minor adverse effects not reported.
Gibbs, 1993[112]	Efficacy of overlapping sphincter repair over a 9 yr period	N: 36 94% 47 yr Mixed 43 mo (4-114 mo)	Serious: Surgical complications in 2 pts (6%); both pts experienced wound sepsis requiring colostomy. Postoperative complications in 11 pts (31%); voiding difficulties, urinary tract infection, perianal sinus tract, and anal stenosis most common. Other: Fever and diarrhea reported in 1 pt (3%).
Keighley, 1984[113]	Efficacy of postanal repair	N: 105 92% 61 yr (median) Mixed 6 mo	Serious: One pt (1%) died following surgery. Wound sepsis reported in 8 pts (8%). Wound infection reported in 9 pts (11%). Skin necrosis reported in 22 pts (25%).Other: Bruising reported in 19 pts (21%).
SNS			
Moya, 2014[114]	Long-term efficacy of sacral nerve stimulation	N: 50 81%	Surgical: Infection at implant site reported in 1 pt (2%). Explant of device required in 3 pts (6%) due to pain at implant site and extremity pain that did

Author, Year	Study Aim	Number of Patients % Female Mean Age/Median* FI Etiology Followup (range)	Adverse Effects of Surgical Treatment: Serious, Other
	(SNS) for FI	64 yr Mixed 55 mo (mean)	not resolve with medical management. Other: Minor adverse effects not reported.
McNevin, 2014[115]	Efficacy of SNS (Interstim) for FI over a 2 yr period	N: 33 91% 63 yr Mixed NR	Surgical: Explant of device in 1 pt (3%) due to chronic pain.
Maeda, 2014[116]	Long-term efficacy of SNS for FI	N: 101 91% 57 yr NR 5 yr	Surgical: By the end of followup, device switched off or explanted in 24 pts (24%); loss of efficacy, lack of efficacy, pain, discomfort, and infection most common. Authors report 521 reportable events in 94 pts (93%); loss of efficacy, lack of efficacy, and pain/discomfort most common. Other: Minor adverse effects not reported.
Feretis, 2013[117]	Mid-term efficacy and safety of SNS for FI	N: 38 95% 62 yr (median) Mixed 16 mo (median) (3-42 mo)	Serious: Authors reported no infections, no major complications during implantation. Reoperation required in 3 pts (8%); need for battery replacement, fractured leads due to falls most common. Short-term complication (<30 d.) in 1 pt (3%); wound-site hematoma. Long-term complications in 24 pts (75%); loss of efficacy, need for re-programming.
Damon, 2013[118]	Long-term efficacy of SNS for FI	N: 119 95% 61 yr Mixed 48 mo (12-84 mo)	Surgical: During followup, explant in 10 pts (8%); lack of efficacy and pain most common reasons. Change in simulator and/or electrode required in 29 pts (24%). Pain reported in 29 pts (24%). Other: Minor adverse effects not reported.
Faucheron, 2012[119]	Efficacy of SNS for patients with both FI & UI	N: 57 95% 58 yr Mixed 63 mo (mean)	Serious: Reoperation required in 16 pts (29%); infection, electrode displacement, pain, battery depletion, and loss of efficacy most common. Complications in 7 pts (12%); details not reported (reported elsewhere). Other: Minor adverse effects not reported.
Pascual, 2011[120]	Short-term efficacy and safety of SNS for FI	N: 50 90% 60 yr Mixed 17 mo (mean)	Serious: Complications reported in 6 pts (12%); wound infection requiring explant, pain, externalization in gluteal stimulator, and broken electrode most common.
Mellgren, 2011[121]	Short- and long-term efficacy and safety of SNS for FI	N: 120 92% 62 yr Mixed 3.1 yr (mean)	Serious: Infection reported in 12 pts (10%). Other: Minor adverse effects reported in 65 pts (54%); implant site pain, paresthesia, and change in sensation of stimulation most common.

Author, Year	Study Aim	Number of Patients % Female Mean Age/Median* FI Etiology Followup (range)	Adverse Effects of Surgical Treatment: Serious, Other
Maeda, 2011[122]	Incidence of suboptimal therapeutic response and adverse effects of SNS used in treatment of FI	N: 176 90% 61 yr(median) NR 11 mo (median) (4-26 mo IQR)	A total of 592 events reported in 150 pts (85%). Explant of device in 31 pts (19%); loss of efficacy, lack of efficacy, pain/discomfort, and infection most common. Most common reportable events were loss of efficacy (212 events in 87 pts [49%]), lack of efficacy (186 events in 68 pts [39%]), and pain or discomfort (126 events in 67 pts [38%]). Other: Constipation in 1 pt (1%), dizziness in 1 pt (1%) were the most common minor adverse effects.
Wexner, 2010[123]	Efficacy and safety of SNS for FI	N: 120 92% 62 yr Mixed 28 mo (2-70 mo)	307 AE occurred in 96 pts related to the device or therapy; 26 were serious. 13 (11%) implant site infections of which 7 needed surgery and 5 of the 7 were device explants; 2 replacements. After implantation, AE in at least 5% of pts: pain, paresthesias and infection most common; urinary incontinence, diarrhea and related sensory changes less common.
Michelsen, 2010[124]	Long-term efficacy and safety of SNS for FI at a single institution	N: 177 90% 60 yr Mixed 24 mo (3-72 mo)	Serious: Infection reported in 2 pts (2%). Failure of device requiring revision in 16 pts (13%). Explant in 15 pts (12%); decreased function, pain, technical failure, and infection most common. Other: Minor adverse effects not reported.
Faucheron, 2010[125]	Determine causes of surgical revision for patients receiving SNS for FI	N: 123 85% 56 yr Mixed 49 mo (2-96 mo)	Serious: Surgical revision required in 36 of 87 pts (41%) receiving permanent implant; infection, electrode displacement or breakage, pain, battery depletion, and loss of clinical efficacy most common reasons. Reoperation due to device malfunction required in 20 pts (24%). Successful revision in 12 pts (14%), explant in 12 pts (14%), details unclear in remaining 12 pts (14%) with surgical revision.
El-Gazzaz, 2009[126]	Efficacy and safety of sacral neuro-modulation on FI symptoms among pts with both UI & FI	N: 24 100% 57 yr NR 28 mo (3-49 mo)	Serious: Complications in 8 pts (33%); infection and lack of clinical response most common reasons; explant in 2 pts (8%). Other: Minor adverse effects not reported.
Hetzer, 2007[127]	Long-term efficacy and safety of SNS for FI	N: 44 68% 65 yr Mixed 13 mo (1-42 mo)	Serious: Complications requiring reoperation reported in 8 pts (22%); seroma, infection, pain, and loss of efficacy most common. Successful re-implant in 5 pts (14%). Other: Sleep disturbances reported in 2 pts (5%).
Rasmussen, 2004[128]	Efficacy and safety of SNS for FI	N: 45 75% 59 yr Mixed 6 mo (median) (0-36 mo)	Serious: Complications reported in 5 pts (14%); infection and lack of clinical response most common reason. Explant required in all 5 pts, and 2 pts with infection awaiting reimplantation at time of manuscript submission. Other: Minor adverse effects not reported.

Author, Year	Study Aim	Number of Patients % Female Mean Age/Median* FI Etiology Followup (range)	Adverse Effects of Surgical Treatment: Serious, Other
Jarrett, 2004[129]	Efficacy of SNS for FI across 3 centers	N: 46 87% 56 yr (median) Mixed 12 mo (median) (1-72 mo)	Serious: Authors report that no major complications were observed. Complications in 8 pts (17%); skin infection, lead displacement, and pain most common. Other: Minor adverse effects not reported.
Kenefick, 2002[130]	Efficacy and safety of SNS for FI over a 5 yr period	N: 15 93% 60 yr Mixed 24 mo (median) (3-60 mo)	Serious: Although authors report no major complications or infections, permanent lead dislodgement requiring reoperation reported in 2 pts (13%). Other: Minor adverse events reported in (27%); pain, superficial skin infection most common.
Mixed/Other			
Boenicke, 2012[131]	Efficacy and safety of SNS for FI pts undergoing stapled transanal rectal resection (STARR)	N: 31 received STARR, 12 SNS 100% 70 yr Mixed 12 mo	Serious: Failure of SNS reported in 6 of 12 pts (50%) who received adjuvant SNS; reasons for failure not reported. Other: Minor adverse effects not reported.
Hultman, 2006[132]	Long-term efficacy of functional gluteoplasty	N: 25 88% 42 yr Mixed 21 mo (3-68 mo)	Serious: Complications reported in 16 pts (64%); dysthesias, cellulitis, irregular contour, abscess, seroma, and fistula most common. Failure of procedure in 2 pts (8%), both of who required permanent ostomy. Other: Minor adverse effects not reported.

AAS=artificial anal sphincter (American Medical Systems AMS 800 urinary sphincter); ABS=artificial bowel sphincter; ACE=antegrade continence enema; AE=adverse event; d=day; FI=fecal incontinence; MACE=Malone antegrade continence enema; mo=months; NR=not reported; pt=patient; pts=patients; SNM=sacral neuromodulation; SNS=sacral nerve stimulation; UI=urinary incontinence; yr=years

Appendix F10. Key Question 1: Benefits of treatment: Summary and strength of evidence of effectiveness and comparative effectiveness of treatments for fecal incontinence in adults by strength of evidence domains*

Intervention	Outcome: Change from Baseline	Number of Studies	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence	Findings
Dietary fiber supplementation with psyllium vs. placebo	FI episodes per week	1 RCT[53] N=206	Low	Consistency unknown (single study)	Direct	Imprecise	Undetected	Low	Psyllium significantly decreased FI by 2.5 episodes per week vs. placebo (0.7 fewer episodes/wk) at 1 month
Clonidine (oral) 0.2mg/day vs. placebo	Mean weekly FICA	1 RCT[52] N=44	Low	Consistency unknown (single study)	Direct	Imprecise	Undetected	Low	No significant difference between groups in FICA improvement at 1 month (1.6 points clonidine vs 1.5 placebo)
PFMT-BF plus estim vs. PFMT-BF	CCFIS	2 RCTs[44,47] N=109	Medium	Consistent	Direct	Imprecise	Undetected	Low	No significant difference between groups in mean CCFIS improvement at 3 months: -1 point in both groups;[44]; -2 points treated, -2.5 points control[47]
	FIQL	2 RCTs[44,47] N=109	Medium	Consistent	Direct	Precise	Undetected	Low	No significant difference in FIQL between groups at 2 to 3 months; neither group improved (0 to 0.3 point change from baseline per subscale)
Dextranomer tissue bulking injections vs. PFMT-BF +/- estim	Vaizey score	1 RCT[64] N=126	Low	Consistency unknown (single study)	Direct	Imprecise	Detected (EQ-5D at 6 mo. NR)	Low	No significant difference between groups in Vaizey improvement at 6 months (-4.6 points dextranomer vs. -5.4 points PFMT-BF)
	FIQL	1 RCT[64] N=126	Low	Consistency unknown (single study)	Direct	Imprecise	Detected (EQ-5D at 6 mo. NR)	Low	No significant difference between groups in FIQL at 6 months (per text and figures; values NR)

Intervention	Outcome: Change from Baseline	Number of Studies	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence	Findings
Dextranomer tissue bulking injections vs. sham injections	CCFIS	1 RCT[39] N=206	Low	Consistency unknown (single study)	Direct	Imprecise	Undetected	Low	No significant difference between treated vs. sham in CCFIS improvement at 3 months (-2.6 points dextranomer vs. -2 sham) and 6 months (-2.5 points dextranomer vs. -1.7 sham)
	FI severity: Percent of patients with ≥50% reduction in FI episodes Median decrease in number of FI episodes/ 2 weeks Mean increase in number of FI-free days	1 RCT[39] N=206	Low	Inconsistent (3 measures gave inconsistent results: 2 better, 1 no different)	Direct	Imprecise	Undetected	Low	Significant difference in percent of patients with ≥50% reduction in FI episodes at 6 months: 52% of dextranomer group vs. 31% sham. Median decrease in number of FI episodes over 2 weeks was not significantly different between groups at 3 months or 6 months (6.0, IQR 0-12.5) vs. 3.0 sham, IQR 0-8.9: p=0.09). Mean increase in number of FI-free days was greater in treated (3.1 days, SD 4.1) vs. sham (1.7 days, SD 3.5) group
	FIQL	1 RCT[39] N=206	Low	Consistency unknown (single study)	Direct	Imprecise	Undetected	Low	Percent improvement from baseline in FIQL coping-behavior subscale favored dextranomer at 6 months: 27% (CI 21%, 34%) vs. sham 11% (CI 3%, 18%). Change scores in 3 other FIQL subscales did not differ (per text and figures, values NR)

Intervention	Outcome: Change from Baseline	Number of Studies	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence	Findings
Durasphere® (off-label) tissue bulking injections vs. non-FDA approved PTQ™ injections	CCFIS	2 RCTs[37,42] N=75	Low (2)	Consistent	Direct	Imprecise	Undetected	Moderate	Moderate evidence that Durasphere® (off-label) injections reduce FI severity at 6 months, and that benefit diminishes between 6 months and 1 year**: 5.3 points at 6wk, 4.1 at 6mo,1.8 at 1y[37]; 3.8 points at 6wk, 5.3 at 6mo, 4.5 at 1y[42]

*Table shows strength of evidence for treatment-outcomes combinations with at least 2 moderate risk of bias RCTs or 1 RCT with low risk of bias and sufficient power to assign low strength of evidence. Other comparisons that had insufficient evidence are not shown in the table.

**Non-FDA approved comparator PTQ™ results are not discussed.

+/- = with or without; BF=Biofeedback; CCFIS=Cleveland Clinic Fecal Incontinence Score; C=Comparator/control; EQ-5D=EuroQoL Questionnaire-5 Dimensions; Estim=Electrostimulation; FI=Fecal incontinence; FIQL=Fecal Incontinence Quality of Life scale; FDA=Food and Drug Administration; M=Mahoney 2004; mo=month; N=Naimy 2007; NR=not reported; PFMT=Pelvic floor muscle training; PTQ™=injectable bulking agent not FDA approved for use in the US; RCT=randomized controlled trial; T=Treatment group Vaizey=Vaizey Fecal Incontinence Score; wk=week

Appendix F11. Risk of bias ratings for randomized clinical trials of fecal incontinence treatments

Author, Year	Intervention	Risk of Bias	Rationale
Bliss 2014[53]	Dietary fiber	Low	Randomized study with allocation concealment; patients and outcome assessors blinded, likely providers too. Adjusted for multiple comparisons; ITT; all relevant outcomes reported; good description of treatments; diagram shows LTF information
Bliss 2001[20]	Dietary fiber	Moderate	Randomization described, single blind study, unclear reporting (whether 42 or 39 patients were randomized, or if the 3 patients who discontinued did so before randomization); primary outcome not specified; ITT. Very limited baseline information on sample (in text).
Lauti, 2008[56]	Dietary fiber and loperamide	Moderate	Low risk of selection bias. Patients and clinicians reportedly blinded but diet advice sheets regarding fiber were common public knowledge at that time (hence, diet unblinded but fiber supplement was deidentified). Non-standardized dietary intervention. Reported ITT but unclear how missing data from 16 was handled in analysis.
Park 2007[57]	Topical phenylephrine	High	Excluded post-randomization data from 6 of 35 with poor compliance. Primary outcome NR. Randomization and allocation low risk. Blinding of pts not possible. Unclear if outcomes assessors were blinded (NR)
Carapeti 2000[63]	Topical phenylephrine	Moderate	Low risk of selection bias. Patients and providers blinded; unclear if outcome assessors blinded. Co-intervention (loperamide) allowed in 42% of patients throughout study; attrition unclear (tables do not show number assessed and LTF NR)
Carapeti 2000[61]	Topical phenylephrine-ileoanal pouch	High	Limited baseline data (in text); patients and providers blinded; blinding of outcome assessors NR; primary outcome NR. Low risk of selection bias. Only period 1 data of crossover were analyzed (washout period may have been insufficient). Cointervention (loperamide) used by 2/3 of sample throughout study
Sun 1997[27]	Loperamide	High	No baseline data, not all outcomes reported and no justification for why FI counts NR; no details on blinding, allocation concealment, or blinding of outcome assessors
Hallgren 1994[14]	Loperamide	Moderate	Limited baseline information (age, sex in text); no baseline values of outcomes, no details on allocation concealment, or blinding of outcome assessors
Read 1982[30]	Loperamide	Moderate	Reported as double blind but no information on randomization mechanism; allocation concealment unclear. No baseline data on outcomes; primary outcome NR.
Palmer 1980[22]	Mixed antidiarrheals	High	No baseline data except etiology; noncompleters excluded from analysis (17%); No information on randomization mechanism; blinding and allocation concealment NR; Primary outcome not specified.
Bharucha 2014[52]	Clonidine	Low	Blinded study, random allocation, low attrition, ITT analysis with methods for missing data, validated outcome measures, all outcomes are reported at 4 weeks.
Pinedo 2012[38]	Zinc-aluminum ointment	Moderate	Unclear risk of bias in several domains due to unclear reporting. Between and within group completer analysis. Needed 48, analyzed 44.
Pinedo 2009[41]	Topical estrogen	Moderate	Double blind stated; NR if outcome assessors were blinded. Randomization method NR. Low attrition; excluded data from 1 placebo pt. who did not complete therapy. All outcomes reported
Kusunoki 1990[25]	Sodium valproate	Moderate	Random order assignment but method not specified. No information on allocation concealment, or whether anyone was blinded. Limited sample, baseline information reported. Primary outcome not specified.

Author, Year	Intervention	Risk of Bias	Rationale
Damon 2014[36]	PFMT-BF	high	Patients lost to followup were excluded from the analysis. Groups unbalanced at baseline for important prognostic factor (history of anorectal surgery). Inadequate randomization detail, allocation NR. Patient and provider blinding not possible.
Norton 2003[33]	PFMT-BF	Moderate	Low risk of selection bias: randomization and allocation concealment acceptable. Blinding of patients and providers not possible. Attrition 18% overall and differed by group (some over 20%); reasons for withdrawal vague. Implications of LTF not discussed. ITT.
Heymen 2009[15]	PFMT-BF	Moderate	No allocation concealment, providers not blinded. Run-in period followed randomization, then treatment failures at run-in commenced interventions with imbalance in group size; baseline considered end of run in and comparability at that point was NR. Attrition 23%.
Whitehead 1985[55]	PFMT-BF	High	Unclear risk of selection bias (randomization and allocation not reported, group comparisons at baseline not reported); no blinding of patients, providers or outcomes assessors, intervention details not described; cointerventions NR, attrition NR.
Ilnyckyj 2005[54]	PFMT-BF	High	Selection bias: unclear risk (randomization and allocation not reported, group comparisons at baseline NR). LTF 22% and no mention of implication of LTF or how missing data handled. No blinding of patients, providers or outcomes assessors.
Bols 2012[65]	PFMT-BF	Moderate	Low risk of selection bias. Patients and providers not blinded; outcome assessors blinded. Multiple providers. High risk of detection bias (followup varied, very underpowered before attrition). ITT.
Solomon 2003[58]	PFMT-BF	High	Provider and patients not blinded to treatment, cointerventions (patients on BF continued previous treatments); handling of missing data NR, analysis of completers likely.
Bartlett 2011[26]	PFMT-BF exercise	High	Groups unbalanced at baseline for important prognostic factor (history of bowel surgery for cancer). Patients blinded but providers and outcomes assessors not blinded. Only 73% of participants analyzed at 2 yr. Randomization and allocation concealment acceptable.
Schwandner 2011[19]	PFMT-BF electrostimulation	Moderate	Providers and patients not blinded; outcome assessors blinded. LTF 11% (reasons for withdrawal vague), select outcomes reported
Schwandner 2010[40]	PFMT-BF electrostimulation	High	Patients who deteriorated were combined with drop outs and no change pts. in analysis; percent who deteriorated were not separately identified. Patients and providers not blinded; outcome assessors blinded. Attrition 61%.
Naimey 2007[44]	PFMT-BF with electrostimulation	Moderate	No baseline characteristics table; no blinding of providers, patients or outcomes assessors. LTF 18%, no mention of how LTF or missing handled. Analysis not ITT.
Mahoney 2004[47]	PFMT-BF with electrostimulation	Moderate	Completer analysis. Pts not blinded, providers blinded, outcomes assessors not blinded; adequate randomization and allocation concealment
Fynes 1999[60]	PFMT-BF with electrostimulation	High	No baseline data, group comparisons at baseline NR, blinding not possible, multiple providers.
Norton 2006[62]	Electrostimulation	Moderate	Poor treatment fidelity; patients, providers and outcomes assessors were unblinded; lacks baseline characteristics by group; attrition 23%
Healy 2006[45]	Electrostimulation	High	Analyzed completers only. Aim was a care site comparison but treatments also differed by group (duration & protocol). Limited baseline characteristics reported. Attrition 17%

Author, Year	Intervention	Risk of Bias	Rationale
Christensen 2006[18]	Transanal irrigation	Moderate	Randomization & allocation low risk; blinding of patients not possible. Weekly interviewer blinded. Cointerventions allowed as needed. ITT. LTF reported overall and by group. Handling of missing data acceptable. No correction for multiple testing. More pts in wheelchairs in control group.
Coggrave 2010[51]	Stepwise bowel management intervention	High	Low risk of selection bias. Blinding not possible. High (35%) overall attrition and unequal by group (attrition higher in treatment group), poor treatment fidelity
Schnelle 2010[17]	Exercise plus diet	High	FI outcome difficult to analyze: 45% of residents did not have a bowel movement during baseline or 10 days post-intervention. Difference between groups at baseline on some important factors. No blinding of patients or providers but validity checks done. Multi-component intervention and multi-center.
Schnelle 2002[16]	Exercise plus incontinence care	High	Low risk of selection bias. Noncompleters dropped from analysis; impact of LTF discussed. High attrition, blinding of patients not possible. FI outcomes not presented for 2 months, only 8 months. Primary outcome not specified
Dehli 2013[64]	Dextranomer injections	Low (to 6 mo)	Low attrition for 6 month analysis. Random allocation and blinded to the extent they were able. PFMT/BF intervention poorly described. ITT analysis with methods for missing data provided. Dismissed 44% of sample at 6 mo. for observational study.
Graf 2011[39]	Dextranomer injections	Low (to 6 mo)	Adequate randomization, blinded (patients and assessors) up to 6 mo, low attrition to 6 mo, sham group had nothing injected (unclear if pts could tell that nothing was injected); Multicenter and multiple providers
Morris 2013[37]	Durasphere injections	Low	Adequate randomization, blinding, allocation concealment; low attrition, sufficient description of treatments, underpowered study (because trial stopped early), lacks demographic information
Tjandra 2009[42]	Durasphere injections	Low	Adequate randomization, allocation concealment; no details on blinding of outcome assessors and not possible to blind surgeons; sufficient description of treatments. No attrition.
Davis 2004[46]	Surgery	High	Patients who withdrew were excluded from analysis; blinding of patients not possible, limited sample information, unclear reporting, 18% attrition.
Hasegewa 2000[49]	Surgery	High	Randomized but no details on method of randomization or allocation concealment. Unclear whether patients and outcome assessors were blinded; blinding not possible for surgeons. Followup varied (no defined assessment point). No baseline table, limited demographic information in text only; no information on co-interventions.
O'Brien 2004[48]	Surgery	High	Blinding not possible; no information on outcome assessor blinding; sparse detail on comparator, no information on co-interventions. Excluded patient failed treatment and required colostomy from analysis. Limited demographic information.
Yoshioka 1999[21]	Surgery	Moderate	No information on blinding of patients or outcomes assessors. Multiple descriptions of followup duration. Primary outcome not specified. Surgeons had limited experience with control surgery. No statistical comparison of between group differences at any time point for any outcome.

Author, Year	Intervention	Risk of Bias	Rationale
Osterberg 2004[29]	Surgery	High	Noncompleters excluded from analysis (16%). LTF differed by group (13% vs. 25%). Blinding of patients and providers not possible; blinding of outcomes assessors NR. No information on co-interventions, primary outcome not specified
van Tets 1998[34]	Surgery	Moderate	Unclear if patients or outcome assessors were blinded. Primary outcome not specified. Multiple descriptions of followup duration (1.5-5 years) but outcomes reportedly assessed at 3 months. No statistical comparison of patient reported outcome measure, no information on allocation concealment, no information on co-interventions
Deen 1993[50]	Surgery	High	No information on allocation concealment, no information on co-interventions, primary outcome not specified, FI frequency not reported at 6mo. and some other data not usable.
Duelund-Jakobsen 2013[31]	SNS	Moderate	Patients blinded; NR if outcomes assessors were blinded. Limited baseline sample information. No adjustment for multiple comparisons. LTF not clearly stated and sample size not reported in results tables. Primary outcome NR.
Duelund-Jakobsen 2012[23]	SNS	High	Randomization NR only allocation concealment; sparse demographic/sample baseline data (in text). Unclear if outcome assessors blinded. Cointerventions NR. 27% attrition.
Tjandra 2008[43]	SNS	Moderate	Patient and provider blinding not possible, primary provider assessed outcomes. Outcomes only partially reported. Randomization and allocation concealment adequate.
Michelsen 2008[24]	SNS	High	No baseline values reported for any measure; crossover RCT but no washout period; excluded data from drop-out. Blinding of outcome assessors NR; not possible to blind patients or providers.
Leroi 2005[28]	SNS	High	Few details on randomization, primary outcome unclear. Patients blinded. Selective reporting: not all outcomes collected were reported; unclear what statistical comparisons being made, no adjustment for multiple comparisons. LTF dropped from analysis (13%)

+/-=with or without; BF=biofeedback; FI=fecal incontinence; ITT=intention to treat analysis; LTF=lost to followup; mo=months; NR=not reported; PFMT=Pelvic floor muscle training; Pts=patients; SNS=sacral neurostimulation

Appendix F12. Risk of bias in fecal incontinence observational studies with comparison group

Author, Year	Treatment	Risk of Bias*	Rationale
Sze, 2009[67]	Fiber & loperamide	High	Comparison group was patients who declined treatment; range and median followup NR; groups differed by unrelated medical history at baseline; prospective study
Remes-Troche, 2008[68]	PFMT-BF + drug	Moderate	Prospective design. Followup duration similar between groups. Comparator group randomly selected from database and matched for gender, age, and FI severity.
Byrne, 2005[69]	PFMT-BF	Moderate	Prospective design. Range of followup NR (median=42 mo). Groups similar at baseline for several characteristics. Lacks some FI severity information at baseline.
Loening-Baucke, 1990[70]	PFMT-BF +/- medical	High	No statistical comparison between group characteristics at baseline; analyses did not control for baseline differences between groups. Prospective design; groups treated at different times (BF: 1983-1985; medical: 1985-1987).
van der Hagen, 2012[71]	Irrigation*	High	Prospective design. Range and median followup NR. Groups differed at baseline on etiology and prior treatments. Analyses conducted and results reported separately by FI type (passive vs soiling). Analyses did not control for baseline differences between groups.
Wong, 2011[74]	Surgery*	High	Wide range of followup (6-72 mo). Median followup differed by group (8 mo vs 22.5 mo). Prospective design.
Dudding, 2009[76]	Surgery	High	Retrospective design. Wide range of followup (1-106 mo). Median followup differed by group (8 mo vs 51 mo).
Steele, 2006[77]	Surgery	High	Retrospective design. Range of followup NR. Mean followup differed by group (27 mo vs 44 mo). Groups differed at baseline on important variables. Wide range of etiologies.
Briel, 1998[80]	Surgery	High	Retrospective design. Range and median followup NR (range at least 10-24 mo). Historical control selected as comparator group (evaluated during 1973-1988 vs 1989-1994). Baseline characteristics not compared between groups. Etiologies NR.
Osterberg, 2000[79]	Surgery	High	Prospective design. Etiology determined treatment allocation. Followup similar between groups. At baseline groups differed by age. Analysis did not control for baseline differences between groups.
Tan, 2001[78]	Surgery	Moderate	Retrospective design. Wide range of followup. At baseline groups similar for key characteristics.
Hong, 2014[72]	Surgery vs. SNS	High	Retrospective design. Wide range of followup (3-138 mo). Mean followup differed by group (50 mo vs 36 mo vs 38 mo). At baseline groups differed by etiology, 2+ failed previous sphincteroplastics, and endoanal ultrasound.
Wong, 2012[73]	Surgery* vs. SNS	High	Comparator group (MAS) had previously failed treatment group procedure (SNS). Retrospective design. Wide range of followup (8-30 mo). Followup differed by group (18 mo vs 2 mo). At baseline groups similar for other key characteristics.
Ratto, 2010[75]	Surgery vs. SNS	High	Retrospective design. Wide range of followup (6-96 mo). Followup differed by group (60 mo vs 33 mo). Age NR at time of procedure.

*Comparator arm non-FDA approved - treatment arm reported only.
FDA=Food and Drug Administration; FI=fecal incontinence; mo=month; NR=Not Reported; SD=standard deviation; SNS=sacral nerve stimulation; yr=year

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